Exhibit 11

State of California ex. rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.

Exhibit to the Declaration of Nicholas N. Paul in Support of
Plaintiffs' Opposition to Defendants' Joint Motion for Partial Summary Judgment

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.* Case No: 1:03-cv-11226-PBS	**Judge Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

DECLARATION OF JEFFREY J. LEITZINGER, PH.D., IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTIONS FOR PARTIAL SUMMARY JUDGMENT

I, Jeffrey J. Leitzinger, do hereby declare as follows:

1. I am an economist and President of Econ One Research, Inc., an economic research and consulting firm. I have master's and doctoral degrees in economics from the University of California at Los Angeles. I have worked as a consultant on economic issues over the past 30 years, a significant portion of which has involved the analysis and calculation of damages. I have personal knowledge of the matters stated in this declaration, and, if called upon to do so, could competently testify thereto.

2. I have been retained by the California Department of Justice to provide consulting services in connection with the State of California's claims against Dey Inc. and Dey L.P. (collectively "Dey"), Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan"), and Sandoz, Inc. ("Sandoz") in the above captioned action,

State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al. Attached hereto as Exhibits A, B, and C are true and correct copies of the June 30, 2009 reports that I prepared for this matter with respect to Dey, Mylan, and Sandoz, respectively ("my reports"). My reports accurately detail the analyses and calculations that I performed in this engagement.

3. Dey, Mylan, and Sandoz (hereinafter collectively referred to as "Defendants") recently filed a joint brief in support of their motions for partial summary judgment. That brief contains the following statement: "[t]here is no evidence in the record to support a claim that California would have ever paid pharmacists less than the FUL [Federal Upper Limit] if Defendants had reported what California contends were the 'true' prices."[1]

4. Using the same Medi-Cal claims data that I use in my reports to determine the amount that Medi-Cal actually reimbursed pharmacies for the relevant Defendants' products (approximately 1.0 million claims for Dey, approximately 14.9 million claims for Mylan, and approximately 12.8 million claims for Sandoz), I have been asked to determine the total number of claims for which the reimbursement price per unit was both less than the FUL and based upon average wholesale price less a statutorily-set discount ("AWP-based reimbursement"). For those claims within this group for which the provider's usual and customary charge to the general public ("billed amount") was less than the estimated acquisition cost ("EAC" or "allowed amount") plus the standard

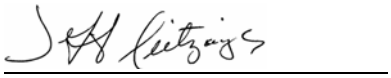
[1] Defendants' Joint Brief in Support of Their Motions for Partial Summary Judgment, November 25, 2009, p. 28.

dispensing fee, I also was asked to determine the number for which that billed amount was equal to the reimbursement amount.

5. I use the variable, "CLM_PMT_CLCTN_DESC" from the Medi-Cal claims data to determine the basis of claim payment. Following the method employed by Sandoz's expert, Dr. Rubinfeld, I treat claim payments indicated as based upon "AWP Minus Percent Amount" or "EAC Amount" as AWP-based reimbursement.[2] I have determined that there are approximately 312,000 claims for which the reimbursement price per unit was less than the FUL,[3] and was based on AWP-based reimbursement. I also have determined for claims within this group that there are approximately 62,000 claims for which the billed amount[4] was less than the allowed amount[5] plus the standard dispensing fee, and was equal to the reimbursement amount.[6]

6. According to these data, therefore, California did pay pharmacists less than the FUL on many occasions.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 18th day of December 2009 in Los Angeles, California.



Jeffrey J. Leitzinger, Ph.D.

[2] See Exhibit D (Expert Report of Daniel L. Rubinfeld, July 30, 2009, pp. 14-15 and Exhibit 2).

[3] As reported in the Medi-Cal formulary file.

[4] Variable named "CLM_BILL_AMT."

[5] Variable named "CLM_ALOWD_AMT_380."

[6] Variable named "CLM_REIMBRSMNT_AMT_349."

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CONFIDENTIAL--TO BE FILED UNDER SEAL
SUBJECT TO PROTECTIVE ORDER

THE STATE OF CALIFORNIA, ex rel. VEN-A-CARE OF THE FLORIDA KEYS, INC., **Plaintiffs,** **v.** **ABBOTT LABORATORIES, INC., et al.** **Defendants.**	**MDL No. 1456** **Master File No. 01-12257-PBS**

EXPERT REPORT OF JEFFREY J. LEITZINGER, PH.D.--DEY

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June 30, 2009

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I. Introduction and Qualifications

1. I am an economist and President of Econ One Research, Inc., an economic research and consulting firm with offices in Los Angeles, Sacramento, Houston, and Washington DC. I have master's and doctoral degrees in economics from UCLA, and a bachelor's degree in economics from Santa Clara University.

2. During the past 30 years of my professional career in economic research and consulting, I have worked extensively on the analysis and calculation of damages. During the past ten years, much of my work has involved projects in the pharmaceutical industry. In that regard, I frequently have been asked to analyze economic issues arising in antitrust cases involving direct purchasers of brand-name drugs who allegedly were overcharged as a result of impaired generic competition. Additionally, I have experience in calculating damages related to the overpayment of Medicaid benefits.

3. I have published numerous articles and reports on economic matters. I have been invited frequently to speak publicly before professional, trade, and regulatory groups as an economist. Additionally, I have testified as an expert economist in various State and Federal courts as well as before a number of regulatory commissions. A detailed summary of my training, past experience, and prior testimony is shown in Exhibit 1.

4. Econ One is being compensated for the time I spend on this matter at the rate of $575 per hour. Econ One also is being compensated for the time spent by research staff on this project based upon contracted hourly rates.

II. Assignment

5. I have been asked to do the following:

a. Determine the amounts (total ingredient costs only) that Medi-Cal[1] actually reimbursed on claims by providers for Dey, Inc. and Dey, L.P. (collectively "Dey") identified pharmaceutical products during the period from January 1, 1994 through December 31, 2004.

b. Determine the amounts (total ingredient costs only) that Medi-Cal would have reimbursed if the reported average wholesale prices ("AWPs") reasonably approximated the actual prices currently paid by the wholesalers' customers for those products over that same time period, insofar as such prices can be determined from Dey's business records. This assumes that, if the reported AWPs had been reasonable approximations of the actual prices paid by the wholesalers' customers, then Medi-Cal would not have

[1] Medi-Cal is California's Medicaid program.

required any offsets from the reported AWPs (i.e., AWP less 5 percent, AWP less 10 percent, AWP less 17 percent).

c. Calculate the State's aggregate overpayment (the difference between using (a) and (b) as the basis for payment), excluding overpayments that arise from any and all claims where the reimbursement amount paid by Medi-Cal (total ingredient costs only) was less than 25 percent above the average net price paid by wholesalers to Dey for the relevant pharmaceutical product.

d. Determine the total number of individual overpaid claims, i.e., the total number of individual claims paid at an amount where there is: i) a positive difference resulting from the calculation in (c); and ii) which collectively comprise the total overpayments calculated in (c).

III. Materials Reviewed

6. For purposes of this report, my staff and I have reviewed electronic transaction-level sales data produced by Dey and electronic Medi-Cal pharmacy claims data produced by the California Department of Health Care Services ("DHCS"). In addition, we have reviewed deposition testimony, produced documents, and pleadings from this (and other related) litigation as well as

publicly available pharmaceutical industry material. A list of the materials that I have relied upon is set forth in Exhibit 2.

IV. Summary of Conclusions

7. I have concluded that total overpayments by the State of California on Medi-Cal reimbursements for Dey identified pharmaceutical products during the period from January 1, 1994 through December 31, 2004 equal $30.1 million.

V. Background

8. California's Medicaid program, Medi-Cal, is a public health insurance program which provides health care services for low-income individuals. As part of its Medi-Cal program, California reimburses pharmacies and other providers, such as intermediate care facilities, that dispense prescription drugs to Medi-Cal participants. The reimbursement to such providers typically consists of two components--the estimated acquisition cost of the drug product and a standard dispensing fee.[2] The estimated acquisition cost is equal to the lowest of the drug

[2] During much of the period at issue here, the basic reimbursement formula was set forth in Section 51513 of Title 22 of the California Code of Regulations. Effective September 30, 2002, that formula first was revised by Section 14105.46 of the California Welfare and Institutions Code. Effective August 16, 2004, that formula again was revised pursuant to Section 14105.45 of that same Code. At all relevant times, if the providers' usual and customary charge to the general public for a prescription was lower than the sum of the estimated acquisition cost and the standard dispensing fee, the provider only was entitled to its usual and customary charge.

Effective January 1, 1995, and continuing through August 31, 2004, the total amount payable to providers under the basic reimbursement formula was reduced by amounts varying from 10 cents to 50 cents per prescription.

product's AWP (less a set percentage), Federal Upper Limit ("FUL"), or California Maximum Allowable Ingredient Cost ("MAIC"). The set percentage deducted from AWP in the basic reimbursement formula varied over time. It was 5 percent from October 16, 1989 through November 30, 2002, 10 percent from December 1, 2002 through August 31, 2004, and 17 percent from September 1, 2004 to date.[3] The standard dispensing fee was $4.05 per prescription until September 2004 when it was raised to $7.25 per prescription (except for prescriptions dispensed in skilled nursing and intermediate care facilities which were raised to $8.00 per prescription).[4]

VI. Medi-Cal Claims Data

9. The data produced by DHCS are pharmacy claims for Medi-Cal's fee-for-service program. These data are contained in the Rebate and Accounting Information System (or RAIS) database which is maintained by DHCS. These data contain claim lines representing each filled prescription which include, among other things, the National Drug Code ("NDC"),[5] the amount that the State

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The various provisions governing the reimbursement amounts paid by Medi-Cal are summarized in documents titled "California Department of Health Services, Medi-Cal Drug Rebate/Dispute Resolution Frequently Asked Questions, Rev. 6/09/05."

[3] California Department of Health Services, Medi-Cal Drug Rebate/Dispute Resolution Frequently Asked Questions, Rev. 6/09/05; see, also, Deposition of J. Kevin Gorospe, 12/3/08, Exs. 20, 23, and 26.

[4] Deposition of J. Kevin Gorospe, 12/3/08, Ex. 26.

[5] The NDC is an 11-digit, 3-segment number that uniquely identifies each drug product distributed in the U.S.

of California reimbursed the pharmacy, the date of service (the date that the prescription was filled), and the service quantity (the number of extended units[6] that the patient received). Claims for service dates that fall in the range from September 1, 1993 through December 17, 2004 are included in these data.

10. These data include 1,561,917 line entries for all Dey NDCs and 1,153,915 line entries for the 28 relevant[7] Dey NDCs (20 products) listed in Exhibit 3. Of those 1,153,915 line entries, the following entries were excluded from my analysis.

- Line entries that represent voids and credit adjustments/reversals, along with the corresponding original claim entries and/or debit adjustments (180,452 entries).[8]
- All line entries that have a service date before January 1, 1994 (10 entries).
- All line entries that relate to compound drugs (21 entries).

[6] An extended unit is defined as the most basic unit measure of volume for a given product, such as a capsule or a gram for drugs sold by weight.

[7] Plaintiffs' counsel provided me with the list of Dey NDCs that are relevant to this lawsuit in a file titled "Current NDC Counts 12-2007.xls." The list includes 32 NDCs, 16 of which relate to eight products (two for each product) that received a new NDC due to packaging enhancements. http://www.dey.com/generics/packagingenhancements/ndcnumber.asp, accessed 2/11/2008. (See Exhibit 3.) For purposes of this report, I have been instructed to ignore the four NDCs related to Epipen (49502050001, 49502050002, 49502050101, and 49502050102).

[8] I use the variable "CLM_DISP_CD_816" to identify voids, credit adjustments/reversals, debit adjustments, and original line entries. I use the variables "CLM_CTRL_NUM_300" and "PRVS_CLM_CTRL_NUM_817" to link the voids, credit adjustments/reversals, and debit adjustments with the original line entries. Voids and credit adjustments/reversals that cannot be linked to an original or debit adjustment line entry are removed from my analysis.

- All line entries that have a non-positive total ingredient cost (5,468 entries).
- All line entries that have a non-zero third-party payment amount (17,816 entries).

This left 950,148 claims.

11. I use these claims to determine the amount that Medi-Cal actually reimbursed pharmacies for the 20 relevant Dey products. The variable "CLM_REIMBRSMNT_AMT_349" provides the total Medi-Cal reimbursement. To determine the ingredient cost component of this reimbursement, I subtract the standard dispensing fee ("CLM_PROFNL_FEE_AMT_381") from the total reimbursement amount.[9] If CLM_PROFNL_FEE_AMT_381 is reported as zero, I subtract $4.05 prior to September 1, 2004 and $7.25 ($8.00 for skilled nursing and intermediate care facilities which are referred to as long-term care claims) thereafter. I divide the reimbursed ingredient cost by the number of extended units to get the reimbursed ingredient cost per extended unit. Next, I multiply that figure by the number of extended units in a package to get the reimbursed ingredient cost per package.[10]

[9] Medi-Cal reimburses pharmacies for ingredient costs plus a standard dispensing fee.

[10] For example, Albuterol Sulfate 0.083% (NDC: 49502069760/49502069761) comes in 3 mL/cc vials. An "extended unit" is one mL/cc (Medi-Cal service quantities are measured in extended units or mL/cc). Each package contains 60 vials or 180 extended units (or 180 mL/cc)--calculated as 60 vials times 3 mL/cc. If a claim has a total reimbursement amount of $75.19, a dispensing fee of $4.05, and a service quantity of 360, then the reimbursed ingredient cost per package is calculated as follows: [($75.19-$4.05)/360]x180=$35.57.

VII. Dey Transaction Data

12. Dey produced electronic transaction-level data reflecting sales of the 20 relevant products from January 2, 1991 through March 30, 2007.[11] These data contain detailed information regarding their transactions with customers including sales, returns, customer rebates, chargebacks, and other customer credits. These data also provide the customer's class of trade (e.g., pharmacy, wholesaler, hospital).

13. In using Dey data to estimate average prices paid by wholesalers' customers for each product, I begin with the prices that wholesalers[12] paid to Dey for each product. I then apply a wholesaler markup to those prices to estimate the total amount that was paid to wholesalers by their customers. These two steps are explained more fully below.

14. In calculating a product specific average net price for wholesalers, it is necessary to take into account certain lump-sum payment adjustments (effectively, price concessions) that are included in the data for each wholesaler

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Prior to October 2002, the Medi-Cal claims processing system could not accept quantities that were not measured in whole numbers. For products measured in decimals, providers were instructed to round up to the nearest whole number. For example, Dey's Metaproterenol 0.6% Solution and Ipratropium Bromide 0.02% Solution products come in 2.5 mL vials. Providers would round up to 3 mL when submitting a claim for reimbursement. The reimbursement amount then was adjusted to reflect the inflated units so that the final amount reimbursed would be correct. (See Declaration of J. Kevin Gorospe, 12/24/08, ¶¶ 3-4.) For claims with inflated units, I adjust those units to get the reimbursed ingredient cost per package.

[11] The date ranges vary by product.

[12] I identified wholesalers by selecting those customers that had "Retail Generic Distrib." or "Wholesaler" for class of trade in the transaction-level data. I excluded 46 transactions that were classified as either "Retail Generic Distrib." or "Wholesaler" that appeared (based on customer name) to be sales to hospitals or medical centers.

as chargebacks, rebates, or other credits.[13] These adjustments are not linked within the data to specific product purchases.

15. A chargeback occurs when the sale price initially recorded for a product purchased by a wholesaler exceeds the price at which that manufacturer has agreed to sell that product to one of the wholesaler's customers. After the wholesaler delivers the product to the customer and receives the contractually-agreed upon payment, the wholesaler then submits a refund claim to the manufacturer for the difference between its acquisition cost (from the manufacturer) and its contract price (to the customer). After processing the chargeback claim, the manufacturer then credits that amount to the wholesaler's account.

16. In the transaction-level data, chargebacks for blocks of past purchases are recorded, following processing, as lump-sum reductions in the balance owed by the wholesaler to the manufacturer. They may not appear in the transaction-level data until several months after the wholesaler purchases that gave rise to them.

17. Rebates and other credits are recorded within the transaction-level data in a similar fashion--i.e., they involve lump-sum credits corresponding to prior purchase activity that appear in the data when issued, with no identification of the prior activity to which they relate.

[13] Returns are dropped from the calculation as they are not always credited at the full current sale price. Prompt payment discounts also are excluded from the net price calculation.

18. Following a convention used by the U.S. government for Medicare reimbursement,[14] I use average payment adjustment percentages over a rolling 12-month period to account for chargebacks, rebates, and other credits. In particular, to calculate the average net price (for any given product) in a given quarter,[15] I first calculate the average payment adjustment percentage over the 12 months preceding the beginning of the quarter. I then obtain the net price for that quarter by taking the average gross price[16] in the immediately preceding quarter and reducing it by the average adjustment percentage.[17]

19. After calculating the average net price per package to wholesalers, I add a wholesaler margin ranging between 3.7 and 5.4 percent[18] to arrive at an estimate of the average wholesale price, i.e., the price that wholesalers' customers pay. See column (5) of Exhibit 4 for estimates of the product specific[19] average net quarterly prices paid by the wholesalers' customers as

[14] See Federal Register, September 16, 2004, Volume 69, Number 179, pp. 55763-55765 for a description of how to calculate the manufacturer's average sales price (ASP).

[15] The price is calculated as of the beginning of a quarter.

[16] Calculated as gross revenue divided by units (the number of packages).

[17] For example, in order to calculate the average net price as of the beginning of 2000Q1, I first aggregate price concessions and gross revenue for January 1, 1999 through December 31, 1999. I then calculate the ratio of price concessions to gross revenue. This ratio then is used to discount the gross price for 1999Q4. For example, if total price concessions equal $100 for January 1, 1999 through December 31, 1999 and total gross revenue equals $400 for that same period, the ratio is 0.25. If the gross price for 1999Q4 is $1.00, then the net price is $0.75 (calculated as $1.00x(1-0.25)).

[18] Based on data contained in the "Industry Profile and Healthcare Factbook," Healthcare Distribution Management Association, various years. See, also, DEY-BO0031296.

[19] Throughout my analysis, I combined the data for the original NDC with the data for the new NDC for each of the eight products that received new NDCs during the period.

determined from Dey transaction-level data. Column (4) of Exhibit 4 depicts the reported AWP, column (6) of Exhibit 4 shows the "spread" (the difference between the average net quarterly prices I have calculated and the reported AWP), and column (7) of Exhibit 4 shows the percentage difference between the average net quarterly prices I have calculated and the reported AWP.

VIII. Calculation of Overpayments

20. To measure overpayments made by the State of California for the 20 relevant Dey products, I first identify those claims for which the actual reimbursement exceeded the average net price paid by wholesalers to Dey by more than 25 percent. For each of these claims, I compare the actual ingredient cost reimbursed (as described above) to an amount that is 25 percent above the average net price paid by wholesalers to Dey.[20] The difference is the overpayment.

21. For certain product/quarter combinations, there are no transactions shown in Dey's data with wholesalers and, hence, there are gaps in my estimates of quarterly average wholesale prices. To fill in these gaps, I refer back to those claims for which there is both a reimbursement amount and a quarterly average wholesale price. I divide total overpayments, as described above, by actual reimbursements from all of the claim lines for the relevant Dey

[20] For claims with inflated extended units (see footnote 10 above), I adjusted the extended units to get the correct service quantities.

products for which I was able to calculate a wholesale price in order to obtain an average overpayment percentage.[21] I then apply this overpayment percentage to the ingredient cost reimbursement for those claims for which I do not have a calculated quarterly average wholesale price and add the resulting figures to the total overpayment amount.

22. Based upon this analysis, the total overpayments by the State of California for all of the 20 relevant Dey products are $30.1 million. That figure, as well as the overpayment for each product, is depicted in Exhibit 5. Exhibit 6A graphically summarizes the calculation of overpayments for a particular Dey product, Cromolyn Nebulizer Solution (NDC: 49502068902/49502068961). This exhibit depicts the reported AWP, the actual reimbursement amount per package, and a reimbursement amount that is 25 percent above the net average price paid by wholesalers to Dey on a per package basis. Exhibit 6B depicts the actual reimbursement amount and a reimbursement amount that is calculated using a price that is 25 percent above the net average price that wholesalers paid to Dey--the difference is the overpayment for the product.

23. The methodology set forth above is economically appropriate for determining losses incurred by Medi-Cal as a direct and proximate result of the inflated AWPs. I am aware that Dey (or experts working on its behalf) has made

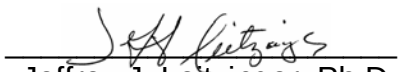
[21] Note, this figure reflects an average overpayment percentage across all relevant Dey claims (for which I had data), not just those claims that were reimbursed at more than 25 percent above the price that wholesalers paid to Dey.

the claim in other cases related to State and Federal reimbursement for its pharmaceutical products that lower reimbursement amounts for estimated acquisition (ingredient) costs also would have had certain indirect effects on program costs. In particular, I understand that Dey (and its experts) have claimed that reduced ingredient cost reimbursement would adversely affect access by program participants to pharmacy services and that this reduction would, in turn, lead Medi-Cal to increase the standard dispensing fee associated with reimbursement. As I understand it, whether or not direct losses incurred by Medi-Cal should be offset by the potential (if any) that accurate ingredient cost reporting would have had other indirect effects on program costs is, as a threshold matter, a legal question.

24. I may supplement this report should Dey present economic evidence in this case regarding the likely occurrence of such effects. At this stage, it seems to me that the requisite economic proof would involve, at minimum, reasonable, non-speculative evidence that: 1) the standard dispensing fees associated with Medi-Cal reimbursement during the period in question here did not cover dispensing costs; 2) reimbursement of ingredient costs at amounts that were no more than 25 percent above net manufacturer prices to wholesalers, taken in combination with the standard dispensing fees that were paid during the period, would not have provided overall reimbursement sufficient to induce pharmacies to dispense Medi-Cal prescriptions; and 3) the resulting decline in

the ability of Medi-Cal participants to access prescriptions would have prompted a decision by Medi-Cal to increase the standard dispensing fee.

25. Exhibit 7 depicts the total number of individual overpaid claims which collectively comprise the total overpayments calculated. Column (3) sets forth the number of claims for which I had Dey transaction data that allowed me to calculate a net average price paid by wholesalers to Dey which resulted in a positive overpayment (i.e., claims in which the actual reimbursement exceeded the net average price paid by wholesalers to Dey by more than 25 percent). Column (4) sets forth the number of claims which contribute to my measure of overpayments for which I do not have a calculated quarterly average wholesale price.



Jeffrey J. Leitzinger, Ph.D.
June 30, 2009

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CONFIDENTIAL--TO BE FILED UNDER SEAL
SUBJECT TO PROTECTIVE ORDER

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EXPERT REPORT OF JEFFREY J. LEITZINGER, PH.D.--MYLAN

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June 30, 2009

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I. Introduction and Qualifications

1. I am an economist and President of Econ One Research, Inc., an economic research and consulting firm with offices in Los Angeles, Sacramento, Houston, and Washington DC. I have master's and doctoral degrees in economics from UCLA, and a bachelor's degree in economics from Santa Clara University.

2. During the past 30 years of my professional career in economic research and consulting, I have worked extensively on the analysis and calculation of damages. During the past ten years, much of my work has involved projects in the pharmaceutical industry. In that regard, I frequently have been asked to analyze economic issues arising in antitrust cases involving direct purchasers of brand-name drugs who allegedly were overcharged as a result of impaired generic competition. Additionally, I have experience in calculating damages related to the overpayment of Medicaid benefits.

3. I have published numerous articles and reports on economic matters. I have been invited frequently to speak publicly before professional, trade, and regulatory groups as an economist. Additionally, I have testified as an expert economist in various State and Federal courts as well as before a number of regulatory commissions. A detailed summary of my training, past experience, and prior testimony is shown in Exhibit 1.

4. Econ One is being compensated for the time I spend on this matter at the rate of $575 per hour. Econ One also is being compensated for the time spent by research staff on this project based upon contracted hourly rates.

II. Assignment

5. I have been asked to do the following:

a. Determine the amounts (total ingredient costs only) that Medi-Cal[1] actually reimbursed on claims by providers for Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan") identified pharmaceutical products during the period from January 1, 1994 through December 31, 2004.

b. Determine the amounts (total ingredient costs only) that Medi-Cal would have reimbursed if the reported average wholesale prices ("AWPs") reasonably approximated the actual prices currently paid by the wholesalers' customers for those products over that same time period, insofar as such prices can be determined from Mylan's business records. This assumes that, if the reported AWPs had been reasonable approximations of the actual prices paid by the

[1] Medi-Cal is California's Medicaid program.

wholesalers' customers, then Medi-Cal would not have required any offsets from the reported AWPs (i.e., AWP less 5 percent, AWP less 10 percent, AWP less 17 percent).

c. Calculate the State's aggregate overpayment (the difference between using (a) and (b) as the basis for payment), excluding overpayments that arise from any and all claims where the reimbursement amount paid by Medi-Cal (total ingredient costs only) was less than 25 percent above the average net price paid by wholesalers to Mylan for the relevant pharmaceutical product.

d. Determine the total number of individual overpaid claims, i.e., the total number of individual claims paid at an amount where there is: i) a positive difference resulting from the calculation in (c); and ii) which collectively comprise the total overpayments calculated in (c).

III. Materials Reviewed

6. For purposes of this report, my staff and I have reviewed electronic transaction-level sales data produced by Mylan and electronic Medi-Cal pharmacy claims data produced by the California Department of Health Care Services ("DHCS"). In addition, we have reviewed deposition testimony,

produced documents, and pleadings from this (and other related) litigation as well as publicly available pharmaceutical industry material. A list of the materials that I have relied upon is set forth in Exhibit 2.

IV. Summary of Conclusions

7. I have concluded that total overpayments by the State of California on Medi-Cal reimbursements for Mylan identified pharmaceutical products during the period from January 1, 1994 through December 31, 2004 equal $104.4 million.

V. Background

8. California's Medicaid program, Medi-Cal, is a public health insurance program which provides health care services for low-income individuals. As part of its Medi-Cal program, California reimburses pharmacies and other providers, such as intermediate care facilities, that dispense prescription drugs to Medi-Cal participants. The reimbursement to such providers typically consists of two components--the estimated acquisition cost of the drug product and a standard

dispensing fee.[2] The estimated acquisition cost is equal to the lowest of the drug product's AWP (less a set percentage), Federal Upper Limit ("FUL"), or California Maximum Allowable Ingredient Cost ("MAIC"). The set percentage deducted from AWP in the basic reimbursement formula varied over time. It was 5 percent from October 16, 1989 through November 30, 2002, 10 percent from December 1, 2002 through August 31, 2004, and 17 percent from September 1, 2004 to date.[3] The standard dispensing fee was $4.05 per prescription until September 2004 when it was raised to $7.25 per prescription (except for prescriptions dispensed in skilled nursing and intermediate care facilities which were raised to $8.00 per prescription).[4]

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[2] During much of the period at issue here, the basic reimbursement formula was set forth in Section 51513 of Title 22 of the California Code of Regulations. Effective September 30, 2002, that formula first was revised by Section 14105.46 of the California Welfare and Institutions Code. Effective August 16, 2004, that formula again was revised pursuant to Section 14105.45 of that same Code. At all relevant times, if the providers' usual and customary charge to the general public for a prescription was lower than the sum of the estimated acquisition cost and the standard dispensing fee, the provider only was entitled to its usual and customary charge.

Effective January 1, 1995, and continuing through August 31, 2004, the total amount payable to providers under the basic reimbursement formula was reduced by amounts varying from 10 cents to 50 cents per prescription.

The various provisions governing the reimbursement amounts paid by Medi-Cal are summarized in documents titled "California Department of Health Services, Medi-Cal Drug Rebate/Dispute Resolution Frequently Asked Questions, Rev. 6/09/05."

[3] California Department of Health Services, Medi-Cal Drug Rebate/Dispute Resolution Frequently Asked Questions, Rev. 6/09/05; see, also, Deposition of J. Kevin Gorospe, 12/3/08, Exs. 20, 23, and 26.

[4] Deposition of J. Kevin Gorospe, 12/3/08, Ex. 26.

VI. Medi-Cal Claims Data

9. The data produced by DHCS are pharmacy claims for Medi-Cal's fee-for-service program. These data are contained in the Rebate and Accounting Information System (or RAIS) database which is maintained by DHCS. These data contain claim lines representing each filled prescription which include, among other things, the National Drug Code ("NDC"),[5] the amount that the State of California reimbursed the pharmacy, the date of service (the date that the prescription was filled), and the service quantity (the number of extended units[6] that the patient received). Claims for service dates that fall in the range from May 17, 1993 through December 17, 2004 are included in these data.

10. These data include 17,691,898 line entries for all Mylan NDCs and 17,687,103 line entries for the 217 relevant[7] Mylan NDCs (217 products) listed in Exhibit 3. Of those 17,687,103 line entries, the following entries were excluded from my analysis.

[5] The NDC is an 11-digit, 3-segment number that uniquely identifies each drug product distributed in the U.S.

[6] An extended unit is defined as the most basic unit measure of volume for a given product, such as a capsule or a gram for drugs sold by weight.

[7] Plaintiffs' counsel provided me with the list of Mylan NDCs that are relevant to this lawsuit in a file titled "Current NDC Counts 12-2007.xls."

- Line entries that represent voids and credit adjustments/reversals, along with the corresponding original claim entries and/or debit adjustments (2,341,444 entries).[8]
- All line entries that have a service date before January 1, 1994 (8 entries).
- All line entries that relate to compound drugs (696 entries).
- All line entries that have a non-positive total ingredient cost (312,336 entries).
- All line entries that have a non-zero third-party payment amount (102,471 entries).
- All line entries that have a total reimbursement amount that is greater than the billed amount (1 entry).

This left 14,930,147 claims.

11. I use these claims to determine the amount that Medi-Cal actually reimbursed pharmacies for the 217 relevant Mylan products. The variable "CLM_REIMBRSMNT_AMT_349" provides the total Medi-Cal reimbursement. To determine the ingredient cost component of this reimbursement, I subtract the standard dispensing fee ("CLM_PROFNL_FEE_AMT_381") from the total

[8] I use the variable "CLM_DISP_CD_816" to identify voids, credit adjustments/reversals, debit adjustments, and original line entries. I use the variables "CLM_CTRL_NUM_300" and "PRVS_CLM_CTRL_NUM_817" to link the voids, credit adjustments/reversals, and debit adjustments with the original line entries. Voids and credit adjustments/reversals that cannot be linked to an original or debit adjustment line entry are removed from my analysis.

reimbursement amount.[9] If CLM_PROFNL_FEE_AMT_381 is reported as zero, I subtract $4.05 prior to September 1, 2004 and $7.25 ($8.00 for skilled nursing and intermediate care facilities which are referred to as long-term care claims) thereafter. I divide the reimbursed ingredient cost by the number of extended units to get the reimbursed ingredient cost per extended unit. Next, I multiply that figure by the number of extended units in a package to get the reimbursed ingredient cost per package.[10]

VII. Mylan Transaction Data

12. Mylan produced electronic transaction-level data reflecting sales of the 217 relevant products from January 3, 1994 through December 30, 2004.[11] These data contain detailed information regarding their transactions with customers including sales, returns, customer rebates, chargebacks, and other customer credits. These data also provide the customer's class of trade (e.g., pharmacy, wholesaler, hospital).

[9] Medi-Cal reimburses pharmacies for ingredient costs plus a standard dispensing fee.

[10] For example, Phenytoin Sodium EXT 100 MG capsule (NDC: 00378156010) comes in 1,000-capsule bottles. An "extended unit" is one capsule (Medi-Cal service quantities are measured in extended units). Each package contains 1,000 extended units. If a claim has a total reimbursement amount of $93.22, a dispensing fee of $4.05, and a service quantity of 360, then the reimbursed ingredient cost per package is calculated as follows: [($93.22-$4.05)/360]x1,000=$247.69.

[11] The date ranges vary by product.

13. In using Mylan data to estimate average prices paid by wholesalers' customers for each product, I begin with the prices that wholesalers[12] paid to Mylan for each product. I then apply a wholesaler markup to those prices to estimate the total amount that was paid to wholesalers by their customers. These two steps are explained more fully below.

14. In calculating a product specific average net price for wholesalers, it is necessary to take into account certain lump-sum payment adjustments (effectively, price concessions) that are included in the data for each wholesaler as chargebacks, rebates, or other credits.[13] These adjustments are not linked within the data to specific product purchases.

15. A chargeback occurs when the sale price initially recorded for a product purchased by a wholesaler exceeds the price at which that manufacturer has agreed to sell that product to one of the wholesaler's customers. After the wholesaler delivers the product to the customer and receives the contractually-agreed upon payment, the wholesaler then submits a refund claim to the manufacturer for the difference between its acquisition cost (from the manufacturer) and its contract price (to the customer). After processing the

[12] I identified wholesalers primarily by selecting those customers that had "AMBULATORY CARE" for class of trade in the IMPCON transaction data, and "Distributors (non-traditional wholesalers)" or "Wholesaler" for class of trade in the Ren transaction data.

[13] Returns are dropped from the calculation as they are not always credited at the full current sale price.

chargeback claim, the manufacturer then credits that amount to the wholesaler's account.

16. In the transaction-level data, chargebacks for blocks of past purchases are recorded, following processing, as lump-sum reductions in the balance owed by the wholesaler to the manufacturer. They may not appear in the transaction-level data until several months after the wholesaler purchases that gave rise to them.

17. Rebates and other credits are recorded within the transaction-level data in a similar fashion--i.e., they involve lump-sum credits corresponding to prior purchase activity that appear in the data when issued, with no identification of the prior activity to which they relate.

18. Following a convention used by the U.S. government for Medicare reimbursement,[14] I use average payment adjustment percentages over a rolling 12-month period to account for chargebacks, rebates, and other credits. In particular, to calculate the average net price (for any given product) in a given quarter,[15] I first calculate the average payment adjustment percentage over the 12 months preceding the beginning of the quarter. I then obtain the net price for

[14] See Federal Register, September 16, 2004, Volume 69, Number 179, pp. 55763-55765 for a description of how to calculate the manufacturer's average sales price (ASP).

[15] The price is calculated as of the beginning of a quarter.

that quarter by taking the average gross price[16] in the immediately preceding quarter and reducing it by the average adjustment percentage.[17]

19. According to DHCS's "price spreading" policy, payment for drugs dispensed is based on a standard package size of 100 tablets or capsules.[18] Therefore, once I calculate the average net price for the standard package size (where available) for each relevant Mylan product, I adjust the average net price for any non-standard package size.[19] For those relevant Mylan products for which there is no standard package size, I do not make any adjustment.

20. After calculating the average net price per package to wholesalers, I add a wholesaler margin ranging between 3.7 and 5.4 percent[20] to arrive at an estimate of the average wholesale price, i.e., the price that wholesalers' customers pay. See column (5) of Exhibit 4 for estimates of the product specific

[16] Calculated as gross revenue divided by units (the number of packages).

[17] For example, in order to calculate the average net price as of the beginning of 2000Q1, I first aggregate price concessions and gross revenue for January 1, 1999 through December 31, 1999. I then calculate the ratio of price concessions to gross revenue. This ratio then is used to discount the gross price for 1999Q4. For example, if total price concessions equal $100 for January 1, 1999 through December 31, 1999 and total gross revenue equals $400 for that same period, the ratio is 0.25. If the gross price for 1999Q4 is $1.00, then the net price is $0.75 (calculated as $1.00x(1-0.25)).

[18] "If a standard package is commercially available, spread the price from the standard package size to the other package sizes. . . . price spreading occurs among National Drug Codes (NDC) for a specific strength and dosage form for specific manufacturer's drug product." OIL # 182-99 (CAAG/DHS-LL0001432-434). See, also, Section 51513 of Title 22 of the California Code of Regulations.

[19] For example, if the average net price for a 100-tablet bottle is $105, then the average net price for each extended unit is $1.05. The average net price for a 500-tablet bottle is $525 (calculated as $1.05X500=$525).

[20] Based on data contained in the "Industry Profile and Healthcare Factbook," Healthcare Distribution Management Association, various years. See, also, CAMylan 00653157, CAMylan 00679702-708, CAMylan 00680169, and CAMylan 02055520.

average net quarterly prices paid by the wholesalers' customers as determined from Mylan transaction-level data. Column (4) of Exhibit 4 depicts the reported AWP, column (6) of Exhibit 4 shows the "spread" (the difference between the average net quarterly prices I have calculated and the reported AWP), and column (7) of Exhibit 4 shows the percentage difference between the average net quarterly prices I have calculated and the reported AWP.

VIII. Calculation of Overpayments

21. To measure overpayments made by the State of California for the 217 relevant Mylan products, I first identify those claims for which the actual reimbursement exceeded the average net price paid by wholesalers to Mylan by more than 25 percent. For each of these claims, I compare the actual ingredient cost reimbursed (as described above) to an amount that is 25 percent above the average net price paid by wholesalers to Mylan. The difference is the overpayment.

22. For certain product/quarter combinations, there are no transactions shown in Mylan's data with wholesalers and, hence, there are gaps in my estimates of quarterly average wholesale prices.[21] To fill in these gaps, I refer back to those claims for which there is both a reimbursement amount and a

[21] For certain product/quarter combinations, the quarterly average wholesale price is negative. The product/quarter combinations with negative prices are treated the same as the product/quarter combinations with missing transaction data for purposes of my analysis.

quarterly average wholesale price. I divide total overpayments, as described above, by actual reimbursements from all of the claim lines for the relevant Mylan products for which I was able to calculate a wholesale price in order to obtain an average overpayment percentage.[22] I then apply this overpayment percentage to the ingredient cost reimbursement for those claims for which I do not have a calculated quarterly average wholesale price and add the resulting figures to the total overpayment amount.

23. Based upon this analysis, the total overpayments by the State of California for all of the 217 relevant Mylan products are $104.4 million. That figure, as well as the overpayment for each product, is depicted in Exhibit 5. Exhibit 6A graphically summarizes the calculation of overpayments for a particular Mylan product, Phenytoin Sodium EXT 100 MG (NDC: 00378156001). This exhibit depicts the reported AWP, the actual reimbursement amount per package, and a reimbursement amount that is 25 percent above the net average price paid by wholesalers to Mylan on a per package basis. Exhibit 6B depicts the actual reimbursement amount and a reimbursement amount that is calculated using a price that is 25 percent above the net average price that wholesalers paid to Mylan--the difference is the overpayment for the product.

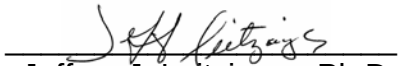
[22] Note, this figure reflects an average overpayment percentage across all relevant Mylan claims (for which I had data), not just those claims that were reimbursed at more than 25 percent above the price that wholesalers paid to Mylan.

24. The methodology set forth above is economically appropriate for determining losses incurred by Medi-Cal as a direct and proximate result of the inflated AWPs. I am aware that Dey, Inc. and Dey, L.P. (collectively "Dey") (or experts working on its behalf) has made the claim in other cases related to State and Federal reimbursement for its pharmaceutical products that lower reimbursement amounts for estimated acquisition (ingredient) costs also would have had certain indirect effects on program costs. In particular, I understand that Dey (and its experts) have claimed that reduced ingredient cost reimbursement would adversely affect access by program participants to pharmacy services and that this reduction would, in turn, lead Medi-Cal to increase the standard dispensing fee associated with reimbursement. As I understand it, whether or not direct losses incurred by Medi-Cal should be offset by the potential (if any) that accurate ingredient cost reporting would have had other indirect effects on program costs is, as a threshold matter, a legal question.

25. I may supplement this report should Mylan present economic evidence in this case regarding the likely occurrence of such effects. At this stage, it seems to me that the requisite economic proof would involve, at minimum, reasonable, non-speculative evidence that: 1) the standard dispensing fees associated with Medi-Cal reimbursement during the period in question here did not cover dispensing costs; 2) reimbursement of ingredient costs at amounts that were no more than 25 percent above net manufacturer prices to

wholesalers, taken in combination with the standard dispensing fees that were paid during the period, would not have provided overall reimbursement sufficient to induce pharmacies to dispense Medi-Cal prescriptions; and 3) the resulting decline in the ability of Medi-Cal participants to access prescriptions would have prompted a decision by Medi-Cal to increase the standard dispensing fee.

26. Exhibit 7 depicts the total number of individual overpaid claims which collectively comprise the total overpayments calculated. Column (3) sets forth the number of claims for which I had Mylan transaction data that allowed me to calculate a net average price paid by wholesalers to Mylan which resulted in a positive overpayment (i.e., claims in which the actual reimbursement exceeded the net average price paid by wholesalers to Mylan by more than 25 percent). Column (4) sets forth the number of claims which contribute to my measure of overpayments for which I do not have a calculated quarterly average wholesale price.



Jeffrey J. Leitzinger, Ph.D.
June 30, 2009

EXHIBIT C

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CONFIDENTIAL--TO BE FILED UNDER SEAL
SUBJECT TO PROTECTIVE ORDER

THE STATE OF CALIFORNIA, ex rel. VEN-A-CARE OF THE FLORIDA KEYS, INC., **Plaintiffs,** **v.** **ABBOTT LABORATORIES, INC., et al.** **Defendants.**	**MDL No. 1456** **Master File No. 01-12257-PBS**

EXPERT REPORT OF JEFFREY J. LEITZINGER, PH.D.--SANDOZ

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June 30, 2009

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I. Introduction and Qualifications

1. I am an economist and President of Econ One Research, Inc., an economic research and consulting firm with offices in Los Angeles, Sacramento, Houston, and Washington DC. I have master's and doctoral degrees in economics from UCLA, and a bachelor's degree in economics from Santa Clara University.

2. During the past 30 years of my professional career in economic research and consulting, I have worked extensively on the analysis and calculation of damages. During the past ten years, much of my work has involved projects in the pharmaceutical industry. In that regard, I frequently have been asked to analyze economic issues arising in antitrust cases involving direct purchasers of brand-name drugs who allegedly were overcharged as a result of impaired generic competition. Additionally, I have experience in calculating damages related to the overpayment of Medicaid benefits.

3. I have published numerous articles and reports on economic matters. I have been invited frequently to speak publicly before professional, trade, and regulatory groups as an economist. Additionally, I have testified as an expert economist in various State and Federal courts as well as before a number of regulatory commissions. A detailed summary of my training, past experience, and prior testimony is shown in Exhibit 1.

4. Econ One is being compensated for the time I spend on this matter at the rate of $575 per hour. Econ One also is being compensated for the time spent by research staff on this project based upon contracted hourly rates.

II. Assignment

5. I have been asked to do the following:

a. Determine the amounts (total ingredient costs only) that Medi-Cal[1] actually reimbursed on claims by providers for Sandoz, Inc. ("Sandoz") identified pharmaceutical products during the period from January 1, 1994 through December 31, 2004.

b. Determine the amounts (total ingredient costs only) that Medi-Cal would have reimbursed if the reported average wholesale prices ("AWPs") reasonably approximated the actual prices currently paid by the wholesalers' customers for those products over that same time period, insofar as such prices can be determined from Sandoz's business records. This assumes that, if the reported AWPs had been reasonable approximations of the actual prices paid by the wholesalers' customers, then Medi-Cal would not have

[1] Medi-Cal is California's Medicaid program.

required any offsets from the reported AWPs (i.e., AWP less 5 percent, AWP less 10 percent, AWP less 17 percent).

c. Calculate the State's aggregate overpayment (the difference between using (a) and (b) as the basis for payment), excluding overpayments that arise from any and all claims where the reimbursement amount paid by Medi-Cal (total ingredient costs only) was less than 25 percent above the average net price paid by wholesalers to Sandoz for the relevant pharmaceutical product.

d. Determine the total number of individual overpaid claims, i.e., the total number of individual claims paid at an amount where there is: i) a positive difference resulting from the calculation in (c); and ii) which collectively comprise the total overpayments calculated in (c).

III. Materials Reviewed

6. For purposes of this report, my staff and I have reviewed electronic transaction-level sales data produced by Sandoz and electronic Medi-Cal pharmacy claims data produced by the California Department of Health Care Services ("DHCS"). In addition, we have reviewed deposition testimony, produced documents, and pleadings from this (and other related) litigation as

well as publicly available pharmaceutical industry material. A list of the materials that I have relied upon is set forth in Exhibit 2.

IV. Summary of Conclusions

7. I have concluded that total overpayments by the State of California on Medi-Cal reimbursements for Sandoz identified pharmaceutical products during the period from January 1, 1994 through December 31, 2004 equal $142.6 million.

V. Background

8. California's Medicaid program, Medi-Cal, is a public health insurance program which provides health care services for low-income individuals. As part of its Medi-Cal program, California reimburses pharmacies and other providers, such as intermediate care facilities, that dispense prescription drugs to Medi-Cal participants. The reimbursement to such providers typically consists of two components--the estimated acquisition cost of the drug product and a standard dispensing fee.[2] The estimated acquisition cost is equal to the lowest of the drug

[2] During much of the period at issue here, the basic reimbursement formula was set forth in Section 51513 of Title 22 of the California Code of Regulations. Effective September 30, 2002, that formula first was revised by Section 14105.46 of the California Welfare and Institutions Code. Effective August 16, 2004, that formula again was revised pursuant to Section 14105.45 of that same Code. At all relevant times, if the providers' usual and customary charge to the general public for a prescription was lower than the sum of the estimated acquisition cost and the standard dispensing fee, the provider only was entitled to its usual and customary charge.

product's AWP (less a set percentage), Federal Upper Limit ("FUL"), or California Maximum Allowable Ingredient Cost ("MAIC"). The set percentage deducted from AWP in the basic reimbursement formula varied over time. It was 5 percent from October 16, 1989 through November 30, 2002, 10 percent from December 1, 2002 through August 31, 2004, and 17 percent from September 1, 2004 to date.[3] The standard dispensing fee was $4.05 per prescription until September 2004 when it was raised to $7.25 per prescription (except for prescriptions dispensed in skilled nursing and intermediate care facilities which were raised to $8.00 per prescription).[4]

VI. Medi-Cal Claims Data

9. The data produced by DHCS are pharmacy claims for Medi-Cal's fee-for-service program. These data are contained in the Rebate and Accounting Information System (or RAIS) database which is maintained by DHCS. These data contain claim lines representing each filled prescription which include,

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Effective January 1, 1995, and continuing through August 31, 2004, the total amount payable to providers under the basic reimbursement formula was reduced by amounts varying from 10 cents to 50 cents per prescription.

The various provisions governing the reimbursement amounts paid by Medi-Cal are summarized in documents titled "California Department of Health Services, Medi-Cal Drug Rebate/Dispute Resolution Frequently Asked Questions, Rev. 6/09/05."

[3] California Department of Health Services, Medi-Cal Drug Rebate/Dispute Resolution Frequently Asked Questions, Rev. 6/09/05; see, also, Deposition of J. Kevin Gorospe, 12/3/08, Exs. 20, 23, and 26.

[4] Deposition of J. Kevin Gorospe, 12/3/08, Ex. 26.

among other things, the National Drug Code ("NDC"),[5] the amount that the State of California reimbursed the pharmacy, the date of service (the date that the prescription was filled), and the service quantity (the number of extended units[6] that the patient received). Claims for service dates that fall in the range from November 12, 1993 through December 17, 2004 are included in these data.

10. These data include 14,907,164 line entries for all Sandoz NDCs, all of which are for the 149 relevant[7] Sandoz NDCs (149 products) listed in Exhibit 3. Of those 14,907,164 line entries, the following entries were excluded from my analysis.

- Line entries that represent voids and credit adjustments/reversals, along with the corresponding original claim entries and/or debit adjustments (1,811,373 entries).[8]
- All line entries that have a service date before January 1, 1994 (2 entries).
- All line entries that relate to compound drugs (1,125 entries).

[5] The NDC is an 11-digit, 3-segment number that uniquely identifies each drug product distributed in the U.S.

[6] An extended unit is defined as the most basic unit measure of volume for a given product, such as a capsule or a gram for drugs sold by weight.

[7] Plaintiffs' counsel provided me with the list of Sandoz NDCs that are relevant to this lawsuit in a file titled "Current NDC Counts 12-2007.xls."

[8] I use the variable "CLM_DISP_CD_816" to identify voids, credit adjustments/reversals, debit adjustments, and original line entries. I use the variables "CLM_CTRL_NUM_300" and "PRVS_CLM_CTRL_NUM_817" to link the voids, credit adjustments/reversals, and debit adjustments with the original line entries. Voids and credit adjustments/reversals that cannot be linked to an original or debit adjustment line entry are removed from my analysis.

- All line entries that have a non-positive total ingredient cost (198,432 entries).
- All line entries that have a non-zero third-party payment amount (81,274 entries).

This left 12,814,958 claims.

11. I use these claims to determine the amount that Medi-Cal actually reimbursed pharmacies for the 149 relevant Sandoz products. The variable "CLM_REIMBRSMNT_AMT_349" provides the total Medi-Cal reimbursement. To determine the ingredient cost component of this reimbursement, I subtract the standard dispensing fee ("CLM_PROFNL_FEE_AMT_381") from the total reimbursement amount.[9] If CLM_PROFNL_FEE_AMT_381 is reported as zero, I subtract $4.05 prior to September 1, 2004 and $7.25 ($8.00 for skilled nursing and intermediate care facilities which are referred to as long-term care claims) thereafter. I divide the reimbursed ingredient cost by the number of extended units to get the reimbursed ingredient cost per extended unit. Next, I multiply that figure by the number of extended units in a package to get the reimbursed ingredient cost per package.[10]

[9] Medi-Cal reimburses pharmacies for ingredient costs plus a standard dispensing fee.

[10] For example, Methylphenidate 10 MG tablet (NDC: 00781174901) comes in 100-tablet bottles. An "extended unit" is one tablet (Medi-Cal service quantities are measured in extended units). Each package contains 100 extended units. If a claim has a total reimbursement amount of $27.69, a dispensing fee of $4.05, and a service quantity of 60, then the reimbursed ingredient cost per package is calculated as follows: [($27.69-$4.05)/60]x100=$39.40.

VII. Sandoz Transaction Data

12. Sandoz produced electronic transaction-level data reflecting sales of the 149 relevant products from January 2, 1996 through December 24, 2004.[11] These data contain detailed information regarding their transactions with customers including sales, returns, customer rebates, chargebacks, and other customer credits. These data also provide the customer's class of trade (e.g., pharmacy, wholesaler, hospital).

13. In using Sandoz data to estimate average prices paid by wholesalers' customers for each product, I begin with the prices that wholesalers[12] paid to Sandoz for each product. I then apply a wholesaler markup to those prices to estimate the total amount that was paid to wholesalers by their customers. These two steps are explained more fully below.

14. In calculating a product specific average net price for wholesalers, it is necessary to take into account certain lump-sum payment adjustments (effectively, price concessions) that are included in the data for each wholesaler as chargebacks, rebates, or other credits.[13] These adjustments are not linked within the data to specific product purchases.

[11] The date ranges vary by product.

[12] I identified wholesalers by selecting those customers that had "004" for class of trade in the AS400 transaction data and "Distributor," "Distributors," or "Wholesalers" for class of trade in the SAP transaction data.

[13] Returns are dropped from the calculation as they are not always credited at the full current sale price.

15. A chargeback occurs when the sale price initially recorded for a product purchased by a wholesaler exceeds the price at which that manufacturer has agreed to sell that product to one of the wholesaler's customers. After the wholesaler delivers the product to the customer and receives the contractually-agreed upon payment, the wholesaler then submits a refund claim to the manufacturer for the difference between its acquisition cost (from the manufacturer) and its contract price (to the customer). After processing the chargeback claim, the manufacturer then credits that amount to the wholesaler's account.

16. In the transaction-level data, chargebacks for blocks of past purchases are recorded, following processing, as lump-sum reductions in the balance owed by the wholesaler to the manufacturer. They may not appear in the transaction-level data until several months after the wholesaler purchases that gave rise to them.

17. Rebates and other credits are recorded within the transaction-level data in a similar fashion--i.e., they involve lump-sum credits corresponding to prior purchase activity that appear in the data when issued, with no identification of the prior activity to which they relate.

18. Following a convention used by the U.S. government for Medicare reimbursement,[14] I use average payment adjustment percentages over a rolling

[14] See Federal Register, September 16, 2004, Volume 69, Number 179, pp. 55763-55765 for a description of how to calculate the manufacturer's average sales price (ASP).

12-month period to account for chargebacks, rebates, and other credits. In particular, to calculate the average net price (for any given product) in a given quarter,[15] I first calculate the average payment adjustment percentage over the 12 months preceding the beginning of the quarter. I then obtain the net price for that quarter by taking the average gross price[16] in the immediately preceding quarter and reducing it by the average adjustment percentage.[17]

19. According to DHCS's "price spreading" policy, payment for drugs dispensed is based on a standard package size of 100 tablets or capsules.[18] Therefore, once I calculate the average net price for the standard package size (where available) for each relevant Sandoz product, I adjust the average net price for any non-standard package size.[19] For those relevant Sandoz products for which there is no standard package size, I do not make any adjustment.

[15] The price is calculated as of the beginning of a quarter.

[16] Calculated as gross revenue divided by units (the number of packages).

[17] For example, in order to calculate the average net price as of the beginning of 2000Q1, I first aggregate price concessions and gross revenue for January 1, 1999 through December 31, 1999. I then calculate the ratio of price concessions to gross revenue. This ratio then is used to discount the gross price for 1999Q4. For example, if total price concessions equal $100 for January 1, 1999 through December 31, 1999 and total gross revenue equals $400 for that same period, the ratio is 0.25. If the gross price for 1999Q4 is $1.00, then the net price is $0.75 (calculated as $1.00x(1-0.25)).

[18] "If a standard package is commercially available, spread the price from the standard package size to the other package sizes. . . . price spreading occurs among National Drug Codes (NDC) for a specific strength and dosage form for specific manufacturer's drug product." OIL # 182-99 (CAAG/DHS-LL0001432-434). See, also, Section 51513 of Title 22 of the California Code of Regulations.

[19] For example, if the average net price for a 100-tablet bottle is $105, then the average net price for each extended unit is $105. The average net price for a 500-tablet bottle is $525 (calculated as $1.05X500=$525).

20. After calculating the average net price per package to wholesalers, I add a wholesaler margin ranging between 3.7 and 5.4 percent[20] to arrive at an estimate of the average wholesale price, i.e., the price that wholesalers' customers pay. See column (5) of Exhibit 4 for estimates of the product specific average net quarterly prices paid by the wholesalers' customers as determined from Sandoz transaction-level data. Column (4) of Exhibit 4 depicts the reported AWP, column (6) of Exhibit 4 shows the "spread" (the difference between the average net quarterly prices I have calculated and the reported AWP), and column (7) of Exhibit 4 shows the percentage difference between the average net quarterly prices I have calculated and the reported AWP.

VIII. Calculation of Overpayments

21. To measure overpayments made by the State of California for the 149 relevant Sandoz products, I first identify those claims for which the actual reimbursement exceeded the average net price paid by wholesalers to Sandoz by more than 25 percent. For each of these claims, I compare the actual ingredient cost reimbursed (as described above) to an amount that is 25 percent above the average net price paid by wholesalers to Sandoz. The difference is the overpayment.

[20] Based on data contained in the "Industry Profile and Healthcare Factbook," Healthcare Distribution Management Association, various years. See, also, SANDOZ WISC 0075546-554 and SANDOZ WISC 0083535-538.

22. For certain product/quarter combinations, there are no transactions shown in Sandoz's data with wholesalers and, hence, there are gaps in my estimates of quarterly average wholesale prices.[21] To fill in these gaps, I refer back to those claims for which there is both a reimbursement amount and a quarterly average wholesale price. I divide total overpayments, as described above, by actual reimbursements from all of the claim lines for the relevant Sandoz products for which I was able to calculate a wholesale price in order to obtain an average overpayment percentage.[22] I then apply this overpayment percentage to the ingredient cost reimbursement for those claims for which I do not have a calculated quarterly average wholesale price and add the resulting figures to the total overpayment amount.

23. Based upon this analysis, the total overpayments by the State of California for all of the 149 relevant Sandoz products are $142.6 million. That figure, as well as the overpayment for each product, is depicted in Exhibit 5. Exhibit 6A graphically summarizes the calculation of overpayments for a particular Sandoz product, Chlorpromazine 100 MG tablets (NDC: 00781171801). This exhibit depicts the reported AWP, the actual reimbursement amount per package, and a reimbursement amount that is 25 percent above the

[21] For certain product/quarter combinations, the quarterly average wholesale price is negative. The product/quarter combinations with negative prices are treated the same as the product/quarter combination with missing transaction data for purposes of my analysis.

[22] Note, this figure reflects an average overpayment percentage across all relevant Sandoz claims (for which I had data), not just those claims that were reimbursed at more than 25 percent above the price that wholesalers paid to Sandoz.

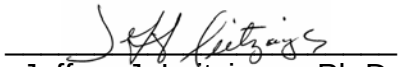
net average price paid by wholesalers to Sandoz on a per package basis. Exhibit 6B depicts the actual reimbursement amount and a reimbursement amount that is calculated using a price that is 25 percent above the net average price that wholesalers paid to Sandoz--the difference is the overpayment for the product.

24. The methodology set forth above is economically appropriate for determining losses incurred by Medi-Cal as a direct and proximate result of the inflated AWPs. I am aware that Dey, Inc. and Dey, L.P. (collectively "Dey") (or experts working on its behalf) has made the claim in other cases related to State and Federal reimbursement for its pharmaceutical products that lower reimbursement amounts for estimated acquisition (ingredient) costs also would have had certain indirect effects on program costs. In particular, I understand that Dey (and its experts) have claimed that reduced ingredient cost reimbursement would adversely affect access by program participants to pharmacy services and that this reduction would, in turn, lead Medi-Cal to increase the standard dispensing fee associated with reimbursement. As I understand it, whether or not direct losses incurred by Medi-Cal should be offset by the potential (if any) that accurate ingredient cost reporting would have had other indirect effects on program costs is, as a threshold matter, a legal question.

25. I may supplement this report should Sandoz present economic evidence in this case regarding the likely occurrence of such effects. At this

stage, it seems to me that the requisite economic proof would involve, at minimum, reasonable, non-speculative evidence that: 1) the standard dispensing fees associated with Medi-Cal reimbursement during the period in question here did not cover dispensing costs; 2) reimbursement of ingredient costs at amounts that were no more than 25 percent above net manufacturer prices to wholesalers, taken in combination with the standard dispensing fees that were paid during the period, would not have provided overall reimbursement sufficient to induce pharmacies to dispense Medi-Cal prescriptions; and 3) the resulting decline in the ability of Medi-Cal participants to access prescriptions would have prompted a decision by Medi-Cal to increase the standard dispensing fee.

26. Exhibit 7 depicts the total number of individual overpaid claims which collectively comprise the total overpayments calculated. Column (3) sets forth the number of claims for which I had Sandoz transaction data that allowed me to calculate a net average price paid by wholesalers to Sandoz which resulted in a positive overpayment (i.e., claims in which the actual reimbursement exceeded the net average price paid by wholesalers to Sandoz by more than 25 percent). Column (4) sets forth the number of claims which contribute to my measure of overpayments for which I do not have a calculated quarterly average wholesale price.



Jeffrey J. Leitzinger, Ph.D.
June 30, 2009

EXHIBIT D

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL Docket No. 1456
THIS DOCUMENT RELATES TO:	)	
State of California ex-rel. Ven-A-Care v. Abbott Laboratories, et al. 03-CV-11226-PBS	)	

EXPERT REPORT OF DANIEL L. RUBINFELD

JULY 30, 2009

I. INTRODUCTION

A. Qualifications

1. I am the Robert L. Bridges Professor of Law and Professor of Economics at the University of California, Berkeley. I served as Deputy Assistant Attorney General at the Antitrust Division of the U.S. Department of Justice from June 1997 through December 1998. In that position, I was responsible for supervising a staff of approximately 70 Ph.D. economists, financial analysts, and research assistants with respect to a wide range of antitrust matters, including monopolization, price fixing, and other restraints of trade.

2. I received my A.B. degree in mathematics from Princeton in 1967 and my Ph.D. in economics from M.I.T. in 1972. I have previously taught at the University of Michigan and have been a Visiting Professor at the law schools of Stanford University, the University of Geneva, the University of Hamburg (on several occasions), the University of Virginia, Catholica University of Lisbon, the University of Bergen, and New York University (on numerous occasions). During the summer of 2003, at the invitation of the Federal Trade Commission, I offered a mini-course on antitrust economics to staff attorneys.

3. I am the author of two textbooks, *Microeconomics* and *Econometric Models and Economic Forecasts* (both with Robert Pindyck). I have received fellowships from the National Bureau of Economic Research, the John M. Guggenheim Foundation, and the Center for Advanced Studies in the Behavioral Sciences. I am a past President of the American Law and Economics Association. I am a current Fellow of the American Academy of Arts and Sciences and a fellow of the National Bureau of Economic Research.

4. My research interests have spanned a range of subject matters, including industrial organization and antitrust policy, public economics, the economics of legal rules and institutions, and law and statistics. I have published or edited seven books and over 100 articles. I have consulted and testified extensively on antitrust, intellectual property, public regulation, and damages issues, for private parties and for the U.S. Department of Justice, the Federal Trade Commission, the U.S. Treasury, and various State Attorney

Generals. My public and private consulting experience includes substantial work relating to the pharmaceutical industry.

5. My teaching interests include antitrust, quantitative methods in law, the economics of legal rules and institutions, economics and public policy. I have served on a number of occasions as a lecturer for the Federal Judicial Center concerning the use of statistical methods by the courts.

6. A current copy of my curriculum vitae is included as Attachment 1. A list of prior testifying experience is included as Attachment 2.

7. I am currently being compensated for my work in this case at the hourly rate of $975. I have no financial interest in the outcome of this matter.

B. Allegations

8. The State of California and a *qui tam* plaintiff, Ven-A-Care of the Florida Keys, Inc. (collectively, "Plaintiffs") allege that the "Defendants defrauded the Medicaid Program of the State of California (known as 'Medi-Cal') by reporting excessively high and false prices for some of their prescription drugs with knowledge that Medi-Cal used these reported prices for establishing reimbursement to its Medi-Cal providers for these drugs." Specifically, Plaintiffs allege that Defendants "reported or caused to be reported false or misleading prices to Medi-Cal by providing false or misleading price information...to the [pricing] compendia including [First DataBank] with knowledge that they [the compendia] in turn would utilize such false and misleading price information in determining the [Average Wholesale Price] and [Direct Price] that were reported to Medi-Cal."[1]

9. As a consequence, Plaintiffs allege that "Medi-Cal sustained significant losses to its program by making payments for the drugs at illegally excessive prices compared to the prices at which the Medi-Cal providers actually acquired the same drugs." Plaintiffs further allege that the "spread" between the reimbursement payments and the actual

[1] *See* First Amended Complaint in Intervention for Money Damages and Civil Penalties for Violations of the California False Claims Act, August 24, 2005 (hereinafter "First Amended Complaint"), pp. 1, 12-13.

acquisition costs of drugs was used by Defendants to "seize market share and thereby to fraudulently increase their profits."[2]

10. Defendant Sandoz Inc. is a pharmaceutical firm that develops, produces, and distributes generic drugs in the U.S. Prior to 2003, Sandoz Inc. was known as Geneva Pharmaceuticals, Inc. In this report, I use "Sandoz" to refer to both entities.

11. Plaintiffs are seeking treble damages, and up to $10,000 for each allegedly false Medi-Cal reimbursement claim. Although the allegations in the First Amended Complaint specific to Sandoz cover the period from January 1, 1994 through the present,[3] I understand that Plaintiffs are seeking damages on prescription claims for the period covering January 1, 1994 through December 31, 2004.[4]

12. I understand further that there are 149 Sandoz drugs, identified by their unique eleven-digit National Drug Codes ("NDCs"), which are covered in the First Amended Complaint[5] and that the relevant Medi-Cal reimbursement claims on which Plaintiffs are entitled to seek damages include only those claims covered under Medi-Cal's fee-for-service plan.[6] On March 22, 2007, the District Court dismissed the First Amended Complaint as it relates to drugs reimbursed based on California's Maximum Allowable Ingredient Cost ("MAIC") methodology.[7] Exhibit 1 shows a list of the top 25 Sandoz NDCs reimbursed by Medi-Cal that are at issue in this case.

C. Assignment

13. I have been asked by Counsel for Sandoz to evaluate various economic issues that flow from Plaintiffs' allegations.

14. Specifically, I have been asked to review the basis used by the State of California for reimbursing Medi-Cal claims for Sandoz drugs, and to evaluate the extent to which the

[2] First Amended Complaint, p. 1.
[3] First Amended Complaint, p. 40.
[4] Expert Report of Jeffrey J. Leitzinger, Ph.D.–Sandoz, June 30, 2009 (hereinafter "Leitzinger Report"), p. 2.
[5] First Amended Complaint, Exhibit D.
[6] Medi-Cal is administered through both a fee-for-service and a managed care plan. *See* Memorandum and Order in re Pharmaceutical Industry Average Wholesale Price Litigation, *State of California vs. Abbott Laboratories*, March 22, 2007.
[7] Memorandum and Order in re Pharmaceutical Industry Average Wholesale Price Litigation, *State of California vs. Abbott Laboratories*, March 22, 2007, p. 32.

state used prices provided by Sandoz in reimbursing Sandoz pharmaceuticals products at issue in this case.

15. In addition, I have been asked to evaluate the information available to the State of California regarding the relationship between benchmark prices and pharmacy acquisition costs. As part of this analysis, I have been asked to consider the relationship between pharmacy acquisition costs and dispensing costs in the context of patient access to Medi-Cal pharmacy services.

16. Furthermore, I have been asked to discuss the economic issues related to the use of benchmark and list prices used in the pharmaceutical industry.

17. Lastly, I have been asked to offer a critique of the damages calculations put forth by Plaintiffs' damages expert, Dr. Jeffrey Leitzinger.

18. A list of the materials that I considered in forming my opinions is included as Attachment 3. I reserve the right to revise or supplement my opinions should additional information become available. I note in particular that at the point I am filing this report, counsel for Defendants have not had the opportunity to depose Dr. Leitzinger.

D. Summary of Conclusions

19. AWP is a benchmark price. Sandoz sets AWP with the primary goal of earning a generic designation from First DataBank. When Sandoz is the first generic entrant, it typically sets AWP at slightly less than 90% of the corresponding branded drug's AWP. When Sandoz is not the first entrant, it typically sets AWP in line with existing generic competitors.

20. WAC is a list price. WAC is the invoice price at which Sandoz sells to wholesalers. It is also the price paid by non-contract customers. List prices are common in many industries, including sticker prices for cars, rack rates for hotel rooms, and cover prices for magazines and newspapers.

21. There has been widespread information available to Medi-Cal officials since at least 1985 making it clear that AWP was not a measure of pharmacy acquisition cost. Medi-Cal officials and other California policymakers testified that they were well aware that acquisition costs were below AWP.

22. The majority of claims for Sandoz drugs reimbursed by Medi-Cal were not paid based on Sandoz reported prices. Over 74 percent of claims were paid based on the FUL and another 12 percent based on pharmacies' usual and customary charges. Only 9 percent of claims were reimbursed based on discounted AWP.

23. Profitability is an important component of pharmacies' decisions to participate in the Medi-Cal program. The profitability of servicing Medi-Cal recipients depends on both the ingredient cost reimbursement and the dispensing fee paid by Medi-Cal. Absent sufficient profitability, pharmacies would not participate in the program.

24. A variety of evidence demonstrates that Medi-Cal's dispensing fee does not cover the dispensing costs of many California pharmacies. This shortfall is particularly significant for low-cost generic drugs. Positive margins on ingredient costs can make up for shortfalls on the dispensing fee side.

25. In Dr. Leitzinger's but-for world, Medi-Cal would reimburse California pharmacies based on average pharmacy acquisition cost. This would ensure that many California pharmacies with above average acquisition costs would lose money, even before accounting for any dispensing fee shortfall. My analysis suggests that, depending on the interpretation of Dr. Leitzinger's but-for world, from 31 to 62 percent of California pharmacies would lose money on Sandoz drugs reimbursed by Medi-Cal, even before accounting for any dispensing fee shortfall.

26. Dr. Leitzinger's calculated "overpayment" is fundamentally flawed as a measure of the alleged injury suffered by the State of California. His analysis fails to consider several issues critical to the proper calculation of damages.

- He only considers the ingredient cost reimbursement and does not consider whether Medi-Cal's dispensing fee is adequate to cover pharmacies' dispensing costs.
- He fails to consider variations in acquisition costs across pharmacies. In fact, as noted above, Dr. Leitzinger's but-for world would ensure that many pharmacies would lose money dispensing Sandoz prescriptions to Medi-Cal recipients.
- He fails to consider alternate reimbursement methodologies that were considered and rejected by Medi-Cal during the relevant period.

- He makes a variety of other methodological errors that substantially inflate his damages estimate.

27. My analysis appears in the sections of this report that follow. I begin in Section II by providing some background on the Medicaid program in general, and on California's Medicaid program, Medi-Cal. In Section III, I detail Medi-Cal's reimbursement methodology, and provide an analysis of Medi-Cal claims reimbursements under Medi-Cal's methodology. In Section IV, I provide a discussion and analysis of the various prices that Sandoz reports to pricing compendia, with a particular focus on AWP. I explain that Medi-Cal was aware that the AWP prices reported by Sandoz to the pricing compendia generally did not represent actual pharmacy acquisition costs. In Sections V and VI, I discuss the relationship between ingredient cost reimbursement and pharmacy dispensing costs, and I show the implication of Dr. Leitzinger's but-for prices for pharmacy profitability. Lastly, in Section VII, I provide a critique of Dr. Leitzinger's analysis of alleged damages.

II. BACKGROUND

A. The Federal Medicaid Program

28. The federal Medicaid program provides medical coverage to eligible lower income individuals and families who have no or inadequate medical insurance. The program is run through the Centers for Medicare and Medicaid Services ("CMS"), under the auspices of the U.S. Department of Health and Human Services.[8] While general guidelines are set by the CMS, states have a great deal of flexibility in the program's design and administration. As part of medical coverage, all state Medicaid programs provide some form of prescription drug benefit.[9] In an outpatient setting, Medicaid recipients take prescriptions from their health care provider to retail pharmacies that choose to participate in the Medicaid program. In general, program costs are split

[8] CMS is the successor to the Health Care Finance Association ("HCFA"). For the remainder of the Report, I will refer to the federal Medicaid administrator as CMS.
[9] See, for example, CMS, "Medicaid Prescription Reimbursement Information by State - Quarter Ending June 2009," <http://www.cms.hhs.gov/Reimbursement/Downloads/reimbursementchart2q2009.pdf>, accessed July 27, 2009.

between the state and the federal government, with the split varying by state and by service type.[10]

B. The Medi-Cal Program

29. Medi-Cal was created in 1966.[11] Prior to July 2007, Medi-Cal was administered by the California Department of Health Services, through its Medical Care Services division.[12] Medi-Cal provides prescription drug benefits under two plans: fee-for-service and managed care, which differ in their patient eligibility and covered population.[13] Under the fee-for-service plan, enrollees may visit any participating pharmacy, where they present their Medi-Cal membership card when getting prescriptions filled. Usually Medi-Cal reimbursement approval is automatic.[14]

30. Pharmacy participation in Medi-Cal is voluntary. However, under federal Medicaid rules, once a pharmacy decides to participate, it must supply all drugs covered by Medi-Cal; it may not provide certain drugs and forego others.[15]

C. Medicaid Rebates

1. Federal rebates

31. Under the Omnibus Budget Reconciliation Act of 1990 ("OBRA '90"), manufacturers wishing to have their pharmaceutical products reimbursed through Medicaid have been required to participate in the Medicaid Drug Rebate Program. Participating generic manufacturers such as Sandoz have been required to pay

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[10] CMS Medicaid Program – General Overview, <http://www.cms.hhs.gov/MedicaidGenInfo/03_TechnicalSummary.asp#TopOfPage>, accessed July 29, 2009.

[11] "*Medi-Cal Facts and Figures – A Look at California's Medicaid Program*," California Health Care Foundation, May 2007, p. 5.

[12] Deposition of Kevin Gorospe, Medi-Cal Pharmacy Policy Chief, (September 22, 2008), (hereinafter "Gorospe Deposition"), pp. 412-427, and Exhibits 032, 033.

[13] Gorospe Deposition (September 22, 2008), pp. 440-442. *See also; Medi-Cal Facts and Figures – A Look at California's Medicaid Program*, California Health Care Foundation, May 2007, p. 26.

[14] Deposition of Larry Bernstein, 30(b)(6), Field Office Chief for Medi-Cal Review Audits and Investigations Program, (December 5, 2008), (hereinafter "Bernstein Deposition"), p. 36. In some cases, the requested prescription must be authorized by the DHCS –a process known as "prior authorization." *See* Deposition of Doug Hillblom, Medi-Cal Staff Services Manager, (September 23, 2008), (hereinafter "Hillblom Deposition"), pp. 32-34

[15] Deposition of Stanley Rosenstein, 30(b)(6), Medi-Cal Chief Deputy Director, (November 6, 2008), (hereinafter "Rosenstein Deposition"), pp. 162-163.

government rebates of 11 percent of the Average Manufacturer Price ("AMP").[16] The AMP is the "average unit price paid to the [m]anufacturer for the drug … by wholesalers for drugs distributed to the retail pharmacy class of trade … AMP includes cash discounts allowed and all other price reductions … which reduce the actual price paid."[17] OBRA '90 required participating manufacturers to report AMPs to CMS effective January 1, 1991.[18] It also required CMS to calculate and to report unit rebate amounts ("URA") on which the rebates under the Medicaid Drug Rebate Program were to be paid.[19]

32. Medi-Cal received information on AMPs from Sandoz, which sent its AMP prices to Medi-Cal from 1991 to 1997.[20] According to Dr. Gorospe, Medi-Cal's chief of pharmacy policy, "Specifically they [CMS] send a file with unit rebate amounts for all NDCs as reported to them by the manufacturers, whether or not California reimbursed the product."[21] Dr. Gorospe went on to testify that Medi-Cal could easily derive the AMP from information provided by CMS.[22]

2. Medi-Cal supplemental rebates

33. The State of California's Supplemental Rebate Program was implemented in the early 1990s.[23] Manufacturers enter into Medi-Cal's supplemental rebate agreements that at times specify the rebate to be a percentage of the AMP.[24]

34. Medi-Cal received AMPs for manufacturers on these types of rebate contracts.[25] Sandoz sent AMP prices as part of its supplemental rebates to Medi-Cal. In at least the fourth quarters of 1994 and 1995, Sandoz paid supplemental rebates to California based

[16] "CMS Medicaid Drug Rebate Program Overview", <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/>, accessed July 27, 2009.
[17] Rebate Agreement Between The Secretary of Health and Human Services and The Manufacturer (Sample), <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/14_NationalDrugRebateAgreement.asp>, accessed July 24, 2009.
[18] Omnibus Budget Reconciliation Act 1990 (OBRA '90) Sec. 1927(b)(3)(A)(i).
[19] Omnibus Budget Reconciliation Act 1990 (OBRA '90) Sec. 1927(b)(2)(A).
[20] SANDOZCALI3000028-1273.
[21] Gorospe Deposition, (September 22, 2008), pp. 713-714.
[22] Gorospe Deposition (September 22, 2008), pp. 713-717.
[23] Deposition of Craig Miller, Medi-Cal Drug Rebate Program Supervisor, (October 22, 2008), (hereinafter "Miller Deposition") p. 221, and Deposition of Mike Namba, DHCS Pharmaceutical Program Consultant, (April 23, 2009), (hereinafter "Namba Deposition"), Exhibit 025.
[24] Gorospe Deposition (March 19, 2008), pp. 71-73.
[25] Hillblom Deposition, pp. 257-258.

on 10 percent of AMP, in the amounts of $236,245.16, and $311,588.33 respectively.[26] In conjunction with these rebates, Sandoz provided Medi-Cal with its AMP prices for those quarters.[27]

III. BASIS OF PAYMENT FOR SANDOZ DRUGS AT ISSUE

A. Medi-Cal's Reimbursement Methodology

35. Generally, Medi-Cal reimbursement for a claim includes payment for pharmacies' acquisition costs for each drug (the "ingredient cost"), plus a payment of a dispensing ("professional") fee.[28] However, under California law, the price reimbursed by Medi-Cal may not exceed the price charged to the general public (the "Usual and Customary" price).[29]

36. Medi-Cal reimburses providers for a drug at the Cost of Drug Product (CDP) plus a dispensing fee, which is the lowest of the drug's Estimated Acquisition Cost (EAC) plus a dispensing fee, the Federal Allowable Cost (FAC) plus a dispensing fee,[30] or the Maximum Allowable Ingredient Cost (MAIC) plus a dispensing fee, for the Standard Package size.[31] Under California law, EAC is "the department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package."[32] Medi-Cal has set EAC equal to AWP minus a determined percentage.[33]

37. The AWP is a price which many drug manufacturers, including Sandoz, provide to various national pricing compendia such as First DataBank and Medi-Span. Medi-Cal has access to AWP prices, as well as Federal Upper Limit (FUL) prices, through FDB.[34]

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[26] Miller Deposition (September 24, 2008), Exhibits 007, 010.
[27] Miller Deposition (September 24, 2008), Exhibits 007, 010.
[28] CAL. CODE REGS. tit. 22, § 51513(b)(l) (2007).
[29] CAL. CODE REGS. tit. 22, § 51513(b)(l)(A) (2007).
[30] Medi-Cal uses the acronym "FAC" to refer to the Federal Upper Limit ("FUL") price. *See* CAL. CODE REGS. tit. 22, § 51513(a)(10) (2007). *See also*, First Amended Complaint, p. 11.
[31] CAL. CODE REGS. tit. 22, § 51513(a)(11) (2007).
[32] CA WEL & INST § 14105.45 Effective 2007.
[33] State Plan Under Title XIX of Social Security Act, Attachment 4.19-B, Supplement A. Since at least 1985, until enactment of Assembly Bill 442, effective December 1, 2002, the EAC for a small number of manufacturers was based on the Direct Price. Sandoz was not one of these. *See* Assembly Bill 442, Chapter 1161, SEC 73(c); Rosenstein Exhibit 8.
[34] Gorospe Deposition (December 3, 2008), pp. 223-226. Medi-Cal received updated AWP figures monthly; however, at a certain point, they started receiving weekly updates.

38. For multiple source drugs, both the Federal Government and the state have methodologies which establish upper bounds on reimbursement. Under Federal regulations, CMS calculates an FUL for drugs in certain circumstances. FULs are used to determine the upper limit for such drugs. The regulations provide for CMS to set the FUL at 150 percent of the lowest listed price in the pricing compendia.[35] However, CMS did not calculate and/or update FULs on a timely basis.[36] Moreover, a CMS witness responsible for calculating FULs has testified that CMS did not always use the lowest published price to set the FUL.[37]

39. The state upper bound, the MAIC, has been set at AWP-5% for the lowest listed AWP price (the "reference price") among therapeutically equivalent drugs.[38] In order to qualify as the reference price Medi-Cal requires that the manufacturer of the reference drug be able to supply Medi-Cal's entire requirements for that drug.[39]

40. The steps used to calculate the total reimbursement are:[40]

1. Determine the Cost of Drug Product as the minimum of the EAC, FUL, or the MAIC for the "Standard Package" size;

2. Add the dispensing fee.[41] If the sum of the Cost of Drug Product and the dispensing fee exceeds the amount the provider charges to the general public, i.e. the provider's billed amount, then reimburse the billed amount;

3. Between January 1, 1995, and August 30, 2004, apply a reduction of varying amounts ($0.10, $0.25, or $0.50) to every claim. (Effective September 1, 2004, the reduction was eliminated.)[42]

41. The following schedule shows the effective date, the percentage discount off AWP (EAC), the applicable dispensing fee, and the reduction per prescription.

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[35] 42 C.F.R. § 447.332(b).
[36] "Omission of Drugs from the Federal Upper Limit List in 2001," OIG, February 2004; *see also* "Addition of Qualified Drugs to the Medicaid Upper Limit List," OIG, December 2004.
[37] Deposition of Sue Gaston , CMS Dispute Resolution Team Lead, (March 19, 2008), pp. 479-480, 498-99.
[38] Effective May 1, 1990. State Plan 89-08 Under Title XIX of Social Security Act, Attachment 4.19-B, Supplement A, p. 3. (Rodriguez Deposition Exhibit 017)
[39] Enrolled Bill Report for Assembly Bill 442, Section 72.
[40] CAL. CODE REGS. tit. 22, § 51513(a), (2007); *see also* "Medi-Cal Drug Rebate - Dispute Resolution Frequently Asked Questions," <http://www.dhcs.ca.gov/PROVGOVPART/Pages/DrugRebateFAQ.aspx#1>, accessed July 23, 2009.
[41] The dispensing fee is the same for brand name and generic pharmaceuticals.
[42] CA WEL & INST § 14105.336 and 14105.337.

Effective Date	EAC	Dispensing Fee	Reduction
Prior to Oct. 16, 1989	AWP-0%	$4.05	
Oct. 16, 1989	AWP-5%	$4.05	
January 1, 1995	AWP-5%	$4.05	$0.50
January 1, 2000	AWP-5%	$4.05	$0.25
July 1, 2002	AWP-5%	$4.05	$0.10
October 1, 2002	AWP-5%	$4.05	$0.50 ($0.10 for nursing homes)
December 1, 2002	AWP-10%	$4.05	$0.50 ($0.10 for nursing homes)
July 1, 2004	AWP-10%	$4.05	$0.10
September 1, 2004	AWP-17%	$7.25 ($8.00 for nursing homes)	Eliminated

42. EAC is based on the Standard Package size. In general, the Standard Package is set at the 100-unit package size.[43] For example, if a Medi-Cal prescription is filled with pills from a 1000-pill package, the AWP applied to that claim for reimbursement will typically be the one associated with the 100-pill package size for that same drug.

B. The Majority of Claims for Sandoz NDCs at Issue Were Not Based On Sandoz' Reported AWP

43. Plaintiffs allege that Sandoz knew that its reported prices for the drugs at issue would be used by Medi-Cal for "establishing reimbursement to its Medi-Cal providers for these drugs."[44] However, in analyzing the claims at issue in this case, I find that the majority were not in fact reimbursed based on the prices directly reported by Sandoz.

44. The claims data produced by the State of California included a field identifying the basis of payment for each claim.[45] Figure 1 below presents a summary analysis of the

[43] CAL. CODE REGS tit. 22, § 51513(a)(8) (2007).
[44] First Amended Complaint, p. 1.
[45] To analyze the claims data produced by the Plaintiffs, I first determined the claims reimbursed at the usual and customary amount. I then relied upon the field, CLM_PMT_CLCLTN_CD_830, in the Medi-Cal claims data to determine the basis of payment on remaining claims. I understand that a value of "4" for the field CLM_PMT_CLCLTN_CD_830 represents claims for which the determined allowed amount was based on MAIC. These claims had apparently already been dropped from the claims data I received. The field CLM_PMT_CLCLTN_CD_830 indicates the "method used to determine the allowed amount." *See*: "Help Text for RAIS Claim Product Universe" and 2007-11-15 Letter Re CA Claims Data.pdf. This field

distribution of the bases of reimbursement for Sandoz drugs at issue, according to this field (See Exhibit 2 for a more detailed presentation).[46] As shown in Figure 1, Medi-Cal reimbursed 74 percent of claims for Sandoz drugs at issue based on the FAC price. Medi-Cal based its reimbursement on AWP in only about 9 percent of claims (about 20 percent of reimbursement dollars).[47] Therefore, for most claims at issue, the ingredient cost calculation did not rely on prices provided by Sandoz.

Figure 1
Medi-Cal Claims: Summary of Basis of Payment (1994-2004)

Basis of Payment	Claims %	Dollars %
FAC	74%	51%
EAC	5%	11%
AWP-Disc	9%	20%
U & C	12%	17%
Other	0%	0%

IV. PRICES REPORTED TO PRICING COMPENDIA

A. AWP is a Benchmark Price

1. AWP reflects a benchmark price used by third-party payers (public and private) as a basis for reimbursement to pharmacies.

45. It has been commonly understood that AWP does not represent the actual average price that a pharmacy pays for branded and generic drugs. With respect to generic drugs, AWP has served a specific function, as explained below.

2. AWP is used by pricing compendia to define a drug's generic status.

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does not indicate if a claim was ultimately reimbursed at U&C, however. Since this is the field relied upon to filter out MAIC-based claims, I conclude that it is reasonable to rely on it to determine Medi-Cal's basis of payment.

[46] This conservatively assumes that claims indicated as based on "EAC" were actually based on AWP-Disc. U&C is calculated as claims where the data field CLM_BILL_AMT is less than CLM_ALOWD_AMT_380 plus CLM_PROFNL_FEE_AMT_381.

[47] Note that this excludes claims based on MAIC, which I estimate to have been approximately 1.8 percent of claims. *See* the readme.txt file provided with the Medi-Cal claims data. The file indicates the number of MAIC claims transactions which were dropped in the data produced by Plaintiffs.

46. FDB produces a data field, the Generic Pricing Indicator ("GPI"), in which FDB classifies a drug as either brand or generic based on the product's reported AWP.[48] The GPI classification is based on a proprietary FDB methodology.[49] Generally speaking, a drug is classified as generic if a manufacturer's AWP is less than about 90% of the corresponding branded AWP.[50]

47. Because generic drugs often receive preferential treatment under both state mandatory substitution laws and under most insurance companies' formularies, Sandoz has a strong interest in having its products classified as generics.[51] According to testimony from numerous Sandoz representatives, when launching a drug, Sandoz sets its AWP with the generic designation in mind and not to affect Medicaid reimbursement.[52] Specifically, when Sandoz is the first generic entrant, Sandoz typically sets AWP at less than 90 percent of the brand-name manufacturer's AWP to ensure that FDB classifies its drugs as generics.[53] When Sandoz is not the first entrant, it sets the AWPs in-line with other generic competitors.[54]

B. WAC is a List Price

48. In the 2003 Medicare Modernization Act, the U.S. Congress described the WAC price as "… the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data."[55] This definition by the Congress reiterated the widely understood meaning of WAC.

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[48] Deposition of Patricia Kay Morgan, FDB Manager of Product Knowledge-Based Services, (January 11, 2005), (hereinafter "Morgan Deposition"), pp. 279-281. According to Ms. Morgan, FDB actually has up to six generic indicator fields.
[49] Morgan Deposition (January 11, 2005), pp 201-203.
[50] Deposition of Kevin Galownia, Sandoz Pricing and Financial Analysis Senior Manager, (June 19, 2008), (hereinafter "Galownia Deposition"), pp. 235-237. Patricia Kay Morgan testified that this percentage is not a "rule," and that generic classification depends on a statistical calculation. *See* Morgan Deposition (August 27, 2007), pp. 98-99.
[51] Deposition of Christopher Worrell, Sandoz Vice President of Sales and Marketing, (August 23, 2007), (hereinafter "Worrell Deposition"), pp. 55-56, 58-60.
[52] Worrell Deposition (August 23, 2007), p. 68.
[53] Worrell Deposition (August 23, 2007), pp. 60-61.
[54] Galownia Deposition (June 19, 2008), pp. 238-240.
[55] Medicare Modernization Act H.R.1-177 Sec.1847A(c)(6)(B), January 7, 2003.

49. Patricia Kay Morgan of First DataBank testified that WAC is "the price that [manufacturer] would list in a catalog or use in a communication to the trade" that does not include discounts.[56] A 1994 GAO study also considered WAC to be a "factory price" that pertains to the undiscounted market segment.[57] Dr. David Kreling also testified that WAC is a list price, and not a net payment by wholesaler to manufacturer.[58] Professor Stephen Schondelmeyer, an expert retained by Plaintiffs in this case, also considered WAC to be a list price. In his 2005 case study on Texas, he reported that list prices, including WAC, "did not offer a reliable method for estimating pharmacies' acquisition costs for prescription drugs."[59]

1. WAC is not a "false" price.

50. WAC is the price at which Sandoz invoices wholesale customers.[60] Moreover, customers who do not have pricing contracts with Sandoz may pay the WAC price. Christopher Worrell testified: "… a certain portion of our business was actually sold at WAC. So, it's not inflated if it's actually a selling price that people are paying. It may be higher than contracts but we actually made sales at those prices."[61]

2. AWP and WAC respond to competition.

51. In response to competitive situations, a generic pharmaceutical manufacturer such as Sandoz may adjust its products' AWPs, and WACs.[62] In fact Sandoz reported AWPs were typically in line with those of its generic competitors.

52. WAC is also set in response to generic competition. As the starting point for pricing to wholesalers, Sandoz has an incentive to keep WAC as high as the market will bear. (Other things the same, a higher WAC will generate higher revenues). However, counterbalancing this are incentives to keep WAC in line with contract prices. Prompt pay discounts are tied to WAC. Chargebacks are determined by the difference between

[56] Morgan Deposition (August 27, 2007), pp. 84-85.
[57] "Prescription Drugs, Companies Typically Charge More in the United States Than in the United Kingdom," GAO, January 1994, pp. 18-20.
[58] Deposition of David Kreling (December 4, 2008), pp. 88-89.
[59] Wrobel, Marian V., Stephen W. Schondelmeyer, et al., "Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Costs," Abt Associates, Inc., September 26, 2005, p. 1.
[60] Galownia Deposition (June 19, 2008), p. 37, *see also* Deposition of Mathew Erick, Cardinal Vice President of Generic Market Development, (June 17, 2008), (hereinafter "Erick Deposition"), p. 119.
[61] Worrell Deposition (May 13, 2008), p. 901.
[62] Worrell Deposition (August 23, 2007), pp. 65-66.

WAC and the contract prices,[63] therefore a lower WAC will reduce the interest costs associated with the chargeback payments.

3. List prices are common in many industries.

53. Many industries use list prices for their products. These prices are often the actual price paid by a given customer. Common examples include sticker prices for cars, rack rates for hotel rooms, and cover price for magazines/newspapers. Typically, in these examples, consumers will actually pay lower prices because providers offer subscription or sales prices. However, these are also the actual prices paid by some consumers.

C. The State of California Was Aware that AWP Did Not Represent Actual Acquisition Cost

1. CMS and third-party reports informed Medi-Cal that AWP did not represent an actual acquisition cost.

54. As early as 1985, CMS was concerned that Medi-Cal "relie[d] so heavily upon AWP as the basis of its EAC."[64] CMS surveyed a sample of Medi-Cal participating pharmacies throughout the state to learn the prices at which these pharmacies were purchasing drugs. The study found that in the aggregate, pharmacies acquired drugs at 16.63% below AWP.[65]

55. In 1987, Medi-Cal changed its reimbursement formula in light of the newly established FULs. In the process of adopting the new regulation, Medi-Cal had access to a Sandoz pricing list with AWP, WAC and the Direct Price for select drugs, as well as contract prices for some Sandoz drugs.[66] The data suggested that AWP did not represent actual acquisition cost. On various strengths of ampicillin, for example, contract prices were on average about 35% below the AWPs.[67] Moreover, there is typically intense price competition between competing generic manufacturers. Where Medi-Cal had access to prices from other generic manufacturers distributing a product that competed with a

[63] Worrell Deposition (August 23, 2007), pp. 104-107, and Galownia Deposition (June 19, 2008), pp. 37, 195-197.
[64] "EAC Survey Report, California Medi-Cal Program, EAC Patrol Initiative," FY85 HCFA Region IX, 1985, p. 3. (Terra Deposition Exhibit 002).
[65] "EAC Survey Report, California Medi-Cal Program, EAC Patrol Initiative," FY85 HCFA Region IX, 1985, p. 6. (Terra Deposition Exhibit 002).
[66] The data were available through a Pharmaceutical Care Network catalog. Rosenstein Deposition Exhibit 033, *see also* Terra Deposition Exhibit 004, 007.
[67] I looked at the following NDCs: 00781125501, 00781255505, 00781299901, and 00781299905. (Terra Exhibit 7, p. 2).

Sandoz product, those prices provided relevant information with respect to the price of Sandoz' competing product.

56. Medi-Cal was asked by CMS to explain Medi-Cal's continued reliance on AWP as a basis for reimbursement.

- In a 1988 letter from an Associate Regional Administrator with CMS, Mr. John Rodriguez, the Deputy Director of the Medical Care Services division at Medi-Cal, was asked to explain Medi-Cal's reference to AWP in setting its EAC "… since there is so much evidence that AWP is not a reliable predictor of what pharmacists actually pay for drugs."[68]
- Similarly, in a 1989 letter from an Associate Regional Administrator with CMS, Mr. Rodriguez was asked to explain and justify Medi-Cal's continued reliance on AWP for setting reimbursement upper limits in light of evidence that AWP did not represent actual prices paid by pharmacies.[69]

57. Moreover, Medi-Cal staff responsible for reimbursement policy had access to and were aware of numerous other reports and analysis, including studies by the State of California, showing that AWP does not represent actual acquisition cost.

- A 1980 GAO report states that "because HHS believed that the AWPs were too high, a primary objective of the EAC program was to get the States away from using [AWPs] as the basis for establishing upper reimbursement limits under their Medicaid drug programs."[70]
- A 1984 report by the OIG, which was transmitted to state Medicaid agencies, stated: "The purpose of this report is to alert Departmental management officials to the opportunity for significant reductions in program expenditures if actions are taken to stop the present widespread use of average wholesale prices (AWP) in determining program reimbursement for prescription drugs. […] HCFA believed that published AWP was too high and, therefore, the purpose of the EAC requirement in the regulations was to move states away from using AWP as the upper limit for reimbursing drug ingredient cost."[71]
- A May 1996 OIG report found that in California AWP exceeded invoice prices overall by 17.5 percent for brand name drugs, and 41.4 percent for generics (based on a sample of 34 pharmacies).[72]

[68] Rodriguez Deposition, Exhibit 009.
[69] Rodriguez Deposition, Exhibit 010.
[70] "Programs to Control Prescription Drug Costs Could be Strengthened," GAO report, (December 1980), p. 37.
[71] "Changes to the Medicaid Prescription Drug Program Could Save Millions" OIG, September 1984, p. 3.
[72] Rosenstein Deposition, Exhibit 005.

- A March 1996 audit performed by the California State Controller's Office in an effort to identify ways Medi-Cal could control costs concluded that the state could save $54 million annually if it were to increase the AWP discount to AWP-10% from AWP-5%.[73] A subsequent "Check-Up" by the State Controller's Office determined that "… the Medi-Cal program continues to pay much more for prescription drugs than is paid by other states and other major purchasers of drugs."[74] The "Check-Up" highlighted California's low discount off of AWP compared with other states.

2. Medi-Cal had access to information regarding the existence and magnitude of generic margins.

58. Medi-Cal had available sources indicating that differences between AWP and actual acquisition costs for generic drugs were generally higher than the differences for branded drugs. Various studies from the OIG reported estimates of acquisition costs for branded drugs and generics. For example, an August 2001 OIG report used data from invoices from calendar-year 1999 from a survey of pharmacies from eight states (excluding California). The report concluded that pharmacy invoice prices were an average of 21.84 percent below AWP for branded drugs.[75] A March 2002 OIG report using the same states and time period found that pharmacy invoice prices were an average of 65.93 percent below AWP for generic drugs. [76]

59. A 2005 OIG study compared reported AWP to AMP using FDB data and CMS data from the first half of 2004. The study found that across NDCs reimbursed by Medicaid, the weighted average generic AWP exceeded AMP by 74 percent compared with 24 percent for single-source brand name drugs.[77]

60. A 1996 Barron's article pointed out the difference in margins for brand versus generic: "For many drugs, especially the growing number coming off patent and going

[73] Rosenstein Deposition, Exhibit 006.
[74] Rosenstein Deposition, Exhibit 007, p. 4.
[75] "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products," OIG, August 2001 (Gorospe Deposition (March 19, 2008), Exhibit 027). *See also* the May 1996 OIG report, Rosenstein Deposition (November 6, 2008), Exhibit 005.
[76] "Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products," OIG, March 2002 (Gorospe Deposition (March 19, 2008), Exhibit 028). *See also*, "Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products," OIG, August 1997.
[77] "Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices," OIG, June 2005, Table 1.

generic, the drug providers actually pay wholesale prices that are 60% - 90% below the so-called average wholesale price, or AWP, used in reimbursement claims."[78]

61. In June 2002 Myers and Stauffer prepared studies of pharmacy reimbursements and drug acquisition costs in California on behalf of the DHCS.[79] At the time of the study, the reimbursement formula was based on AWP-5% with a $4.05 dispensing fee. According to Myers and Stauffer's analysis of year-2000 invoices, the average actual acquisition cost across pharmacies was 82.8% of AWP for single source drugs based on invoices from external wholesalers.[80] In contrast, for multi-source drugs, the average actual acquisition cost for drugs with a FUL was 14.1% of AWP, and for drugs without a FUL was 64.6% of AWP.[81]

3. California policy-makers were aware that AWP does not represent actual acquisition cost.

62. Several Medi-Cal representatives, including high-ranking individuals, testified that they understood that AWP does not and did not reflect actual pharmacy acquisition costs for drugs.

- Doug Hillblom, a staff services manager at Medi-Cal, testified that "Q: … at the time you joined the California Department of Health Services … [y]ou understood that for drugs … with which you were familiar AWP on average was higher than the provider's acquisition costs for the drug? A: Correct."[82]
- Kevin Gorospe testified that "Q: So when you went to work for the state, it was your understanding, at least in your experience, that when pharmacies acquire drugs from manufacturers, that they were paying something less than AWP? … A: Yes."[83]

63. Members of the California Legislature and of the Governor's office also understood that the AWP was not a good measure of actual acquisition costs. Moreover, this

[78] "Hooked on Drugs," Barron's, June 10, 1996.
[79] *A Survey of Acquisition Costs of Pharmaceuticals in the State of California* (hereinafter "Myers and Stauffer, Acquisition Costs"), and *Study of Medi-Cal Pharmacy Reimbursement* (hereinafter "Myers and Stauffer, Pharmacy Reimbursement"), Myers and Stauffer, LC., Prepared for the California Department of Health Services, June 2002.
[80] Myers and Stauffer, Acquisition Costs, Exhibit 9.
[81] Myers and Stauffer, Acquisition Costs, Exhibits 12 and 13.
[82] Hillblom Deposition, p. 58.
[83] Gorospe Deposition (March 19, 2008) pp. 57-58.

awareness was clearly reflected in policy discussions regarding Medi-Cal's reimbursement policy.

- Stanley Rosenstein testified that the March 1996 audit by the California State Controller's Office was well publicized: "It was very much put in the public domain and debated and in the press. It was a fairly controversial report." He testified that Department of Health Services received numerous inquiries about the report from California Legislators.[84]
- The findings behind a 1995/1996 request for approval for proposed legislation to increase the discount on AWP and add a WAC component to the calculation of reimbursement, highlighted the fact that AWP was high relative to actual acquisition costs. The request had been signed by the Governor's office.[85]

64. In sum, California policy-makers at all levels were clearly aware (well before the start of the damages period) that AWP did not represent an actual price, and could not be an appropriate measure of EAC.

V. MEDI-CAL DISPENSING FEES AND PHARMACY PROFITABILITY

A. Medicaid Statute Mandates Patient Access to Medicaid Pharmacy Services

65. Since pharmacies participate in Medi-Cal on a voluntary basis, the reimbursement formula established by Medi-Cal must be sufficient to "enlist enough providers so that care and services are available … at least to the extent that such care and services are available to the general population in the geographic area."[86] From an economic perspective, the willingness for a pharmacy to participate in Medi-Cal depends fundamentally on the total reimbursements – including ingredient cost reimbursement and dispensing fee – that the pharmacy receives on prescriptions. Adequate compensation for pharmacies is essential for Medi-Cal to provide access to recipients and satisfy the rules established under the federal statute.

B. It is Important to Evaluate the Reimbursement System as a Whole

66. In order for the sale of a drug under Medi-Cal to be profitable for a pharmacy, the pharmacy must be able to cover not only the cost of acquiring pharmaceuticals, but also other costs. Therefore, profitability requires that any shortfall in dispensing fees be off-set ("cross-subsidized") by higher reimbursements on ingredient costs.

[84] Rosenstein Deposition, pp. 100-104.
[85] Rosenstein Deposition, Exhibit 010, p. 123.
[86] 42 U.S.C. § 1396a(30)(A).

67. This was understood by federal Medicaid officials. For example, in a 1990 letter, Ms. Kathleen Buto, CMS's Director of the Bureau of Policy Development, explained: "[a]t the present time, we [CMS] fully expect that as states establish Estimated Acquisition Costs (EAC) at Average Wholesale Price (AWP) less a significant discount there will be added pressure to increase dispensing fees."[87]

68. Moreover, as Leonard Terra, former Chief of the Pharmacy Unit in the Medi-Cal Policy Division, testified: "Overall reimbursement to pharmacy providers is not only the ingredient cost side of the reimbursement but their dispensing fee. And to the extent that you adjust one side of the equation, it may affect the other side of the equation in terms of overall reimbursement to pharmacies … To provide access to drugs, we need pharmacies that participate in Medi-Cal, and they will participate depending on overall reimbursement and adequacy of that."[88]

C. Medi-Cal Dispensing Fees Do Not Cover Dispensing Costs for Many Pharmacies

69. There is substantial evidence that in many states, including California, Medicaid dispensing fees have been set at levels insufficient to cover the costs of many pharmacies. This is especially true for high-cost pharmacies.

70. For example, a 2004 report prepared by Drs. Stephen Schondelmeyer and Marian Wrobel, with help from a panel of experts selected in consultation with CMS, indicated that with respect to Medicaid, "dispensing fees are lower than actual dispensing costs and that drug payment generally exceeds actual acquisition costs." The panel concluded that "[t]he spread in drug payment compensates for the low dispensing fees," and that "[i]f it weren't for the spread, pharmacies would be out of business."[89]

71. Third-party studies which have included California pharmacies have estimated pharmacy dispensing costs that are much higher than the dispensing fees paid by Medi-Cal.

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[87] Deposition of Kathleen Buto, (September 12, 2007), Dey Exhibit 101.
[88] Deposition of Leonard James Terra, Medi-Cal Chief of Pharmacy Unit, (December 4, 2008), (hereinafter "Terra Deposition"), pp. 114-115.
[89] Schondelmeyer, Stephen W. and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices, Final Report*, Abt Associates, Inc., August 30, 2004, Appendix. B-2. The panel was basing its conclusions on a general industry understanding.

1. The Purdue Study

72. In 1989 and 1990, Purdue University researchers surveyed 751 chain pharmacies across the United States in order to estimate the average total cost to a pharmacy of dispensing a prescription. The surveys were developed with the help of the National Association of Chain Drug Stores ("NACDS") staff and executives from chain pharmacies, and were sent via mail to a random sampling of chain pharmacies. Financial data from the surveys was incorporated into a model designed to account for both the direct and indirect costs associated with the operation of pharmacies and the dispensing of prescriptions. The study found that pharmacies in the west region on average were incurring $5.97 in dispensing costs per prescription.[90]

2. The Myers and Stauffer Study

73. In June 2002, a Myers and Stauffer study commissioned by Medi-Cal considered the relationship between actual pharmacy dispensing costs and Medi-Cal dispensing fees.[91] The study reported that in California Medi-Cal's reimbursement for ingredient costs were generally higher than what pharmacists paid for drugs, and Medi-Cal's dispensing fee was significantly lower than the average dispensing costs. The study argued that "… both dispensing fee and ingredient reimbursement rates should be considered in tandem …"[92]

74. Specifically, Myers and Stauffer found that in 2002 the unweighted median pharmacy dispensing cost among all included pharmacies was $7.40 per prescription[93] and the unweighted average dispensing costs was $7.87. Moreover, Myers and Stauffer reported that 75 percent of pharmacies sampled had dispensing costs of between $5 and $10.[94]

75. Furthermore, Myers and Stauffer determined that the difference in the unweighted average dispensing cost between low-volume pharmacies (at $10.02) and high volume

[90] West region consisted of Alaska, Arizona, California, Colorado, Idaho, Hawaii, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming. "An Assessment of Chain Pharmacies' Costs of Dispensing a Third Party Prescription," Pharmaceutical Economics Research Center, Purdue University, May 1990, p. 113.
[91] Myers and Stauffer, Pharmacy Reimbursement.
[92] Myers and Stauffer, Pharmacy Reimbursement, p. 6.
[93] The dispensing cost estimate is for pharmacies that do not dispense intravenous and compounding medications. Myers and Stauffer, Pharmacy Reimbursement, p. 28.
[94] Myers and Stauffer, Pharmacy Reimbursement, pp. 26-28.

pharmacies (at $6.92) was $3.10 per prescription.[95] Thus, low-volume pharmacy costs were, on average, 45% higher than high-volume pharmacy costs.

76. The Myers and Stauffer results indicate that, given Medi-Cal's $4.05 dispensing fee, a majority of the pharmacies participating in Medi-Cal at that time were not being adequately compensated for their dispensing costs.

77. Based on these studies, Myers and Stauffer recommended that the DHCS "should consider increasing the discount from the Average Wholesale Price (AWP) for both single source and multi-source drugs."[96] They also recommended that the dispensing fee should be raised "[s]hould the [DHCS] desire to more closely match the pharmacy dispensing fee with observed pharmacy dispensing cost …"[97]

3. The Grant Thornton Study

78. A 2007 study by Grant Thornton surveyed 23,152 pharmacies to quantify the costs incurred by pharmacies in dispensing prescriptions. Grant Thornton analyzed prior studies, interviewed an expert panel consisting of academics and state Medicaid experts, and visited a variety of pharmacies.[98]

79. The study concluded that the average cost to dispense a Medicaid prescription by California pharmacies was $13.18, with a 25th percentile of $10.92, and a 75th percentile of $14.12.[99] The study also includes dispensing cost comparisons for low volume and high volume pharmacies as well as for rural and urban pharmacies. When the cost of dispensing is computed on a per-pharmacy basis, the mean cost for low volume pharmacies is $14.84 per prescription and for high volume pharmacies, $9.01 per prescription. Similarly, the mean dispensing cost per prescription is $10.90 for rural pharmacies and $12.30 for urban pharmacies.[100]

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[95] Myers and Stauffer, Pharmacy Reimbursement, p. 29. Low-volume pharmacies are those that dispensed fewer than 30,000 prescriptions in the year 2000, and high-volume pharmacies are those that dispensed 60,000 or more prescriptions.
[96] Myers and Stauffer, Pharmacy Reimbursement, p. 5.
[97] Myers and Stauffer, Pharmacy Reimbursement, p. 6.
[98] "National Study to Determine Dispensing Prescriptions in Community Retail Pharmacies," Grant Thornton, January 26, 2007.
[99] "National Study to Determine Dispensing Prescriptions in Community Retail Pharmacies," Grant Thornton, January 26, 2007, p. 30.
[100] "National Study to Determine Dispensing Prescriptions in Community Retail Pharmacies," Grant Thornton, January 26, 2007, pp. 17, 20.

80. At the time of this study, the dispensing fee for Medi-Cal was $7.25 for most pharmacies. Although the fee had been increased in 2004, it was not sufficient to cover dispensing costs of many pharmacies.

81. It is clear that Medi-Cal's dispensing fee was not adequately compensating many participating pharmacies for their dispensing costs. If pharmacies were to find it profitable to participate in Medi-Cal programs, this deficit would have to be made up for by reimbursements that exceeded ingredient costs.

D. Subsidizing the Shortfall in Dispensing Fees May Require a Substantial Percentage Margin on Ingredient Costs

82. In order to cross-subsidize the shortfall in dispensing costs, pharmacies require substantial margins on the ingredient costs. This is particularly true for generic drugs, whose ingredient costs are generally lower, and often substantially lower than the ingredient costs on branded drugs.

83. Consider a generic drug with a pharmacy acquisition cost of $2 per prescription and a dispensing cost of $7.40 per prescription, as estimated by Myers and Stauffer for 2000. $7.40 is $3.35 more than the $4.05 California dispensing fee. In this case, the pharmacy requires reimbursement for the ingredient cost of at least $5.35 ($2.00 plus $3.35) to break even on prescriptions of this drug. This represents a margin of 168%.

E. Access Issues Played a Prominent Role in Medi-Cal's Policy Discussions Regarding Reimbursement

1. Adequate access was important to state officials considering reimbursement policy.

84. It is clear from the evidence that access to pharmacy services has been a primary concern of state officials when considering reimbursement policy.

- Mr. Rosenstein testified that the DHCS had taken a position against a proposed California Assembly Bill, AB1915, which would have increased the percentage discount on AWP from 5% to 15% for calculating EAC, because of concerns that it would negatively affect patient access in violation of federal law.[101]
- Dr. Gorospe testified that a goal of the Medi-Cal program is "to ensure that recipients have access to care," and a way of reaching this goal is to ensure that there are an adequate number of providers participating in the

[101] Rosenstein Deposition, Exhibit 014, pp. 153-155.

program.[102] According to Dr. Gorospe, "before Medi-Cal makes decisions on changes in policy, … it wants to satisfy itself that whatever change is being proposed is not going to negatively impact access to care."[103]

- Dr. Gorospe testified that "providers were concerned about any proposed reductions in reimbursement because it would impact their ability to either participate in the Medi-Cal program, or in some instances, to stay in business."[104]
- A Task Force was established at the initiative of the California Health and Welfare Agency to consider Medi-Cal cost-saving options to be considered as part of the Governor's budget.[105] Members of the Task Force included representatives from the California Legislature, the Department of Health Services, government officials and members of the medical and pharmaceutical industries.[106] Although ideas for revising the reimbursement methodology were considered, the Task Force was apparently not very enthusiastic. A summary of Task Force recommendations stated that "[t]he Task Force had many misgivings about implementing either of these two options [reducing reimbursement to AWP-15% from AWP-5%, or basing reimbursement on WAC]. While the proposals do save money, Task Force members noted that these would risk reducing Medi-Cal beneficiaries' access to pharmacy services as pharmacies withdraw from Medi-Cal participation or go out of business."[107]
- Mr. Rosenstein testified that Medi-Cal's 2004 changes to its reimbursement formula, including a combination of raising the AWP discount to AWP-17% and raising the dispensing fee to $7.25 ($8.00 for nursing homes), were in direct response to Myers and Stauffer's 2002 study.[108]

2. Pharmacy groups expressed concern about lowering the ingredient reimbursements.

85. California pharmacists repeatedly expressed concern that lowering ingredient reimbursements (without increasing dispensing fees) would lead some pharmacies to stop participating in the Medi-Cal program.

86. For example, in a letter dated March 23, 1988, to a California State Senator, the California Pharmacists Association ("CPhA") argued that a proposal to base

[102] Gorospe Deposition (March 19, 2008), pp. 112-115.
[103] Gorospe Deposition (March 19, 2008), pp. 113-118.
[104] Gorospe Deposition (March 19, 2008), p. 119.
[105] Rosenstein Deposition, pp. 54-55; Gorospe Deposition (March 19, 2008), pp. 142-143.
[106] Rosenstein Deposition, pp. 171-174, Exhibit 017.
[107] Rosenstein Deposition, Exhibit 024.
[108] Rosenstein Deposition, pp. 228-232, 240-241.

reimbursement on actual acquisition cost rather than AWP would "result in several independent pharmacies in California being forced out of business."[109]

87. More recently, in a letter dated February 22, 2000, to a California Legislator, California Advocates, Inc., on behalf of CPhA, lobbied against a proposal, AB1915, to lower reimbursement from AWP-5% to AWP-15%. California Advocates, Inc. stated that "… many pharmacies will *not* accept a reimbursement level that is lower that their cost of doing business and in many cases will cease to participate in the Medi-Cal program. Many pharmacies in rural or inner-city regions that serve a high volume of Medi-Cal patients will be put out of business."[110]

88. Indeed, as mentioned above, Medi-Cal also opposed the bill, citing conflict with federal law with respect to maintaining an adequate network of providers.[111] The change to AWP did not occur.

89. The response by pharmacies to CMS's recent proposal to revise the methodology for calculating FULs provides further evidence of the importance of adequate reimbursement to pharmacy participation in the Medicaid program. CMS proposed replacing the existing methodology for calculating FULs (150% of lowest published price) with 250% of AMP. Pharmacists sued CMS arguing that the new methodology would substantially reduce reimbursements to pharmacists and as a result potentially "limit access to medications and pharmacy services."[112] Interestingly, Professor Schondelmeyer filed a report on behalf of the pharmacists concluding: "Reductions in payments will result in substantial loss, and even closures, for a number of pharmacies. In total, a loss of 20% of all retail pharmacies would not be unexpected from payment cuts of the magnitude that will result from the final rule."[113]

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[109] Gorospe Deposition (March 19, 2008), Exhibit 007.
[110] Gorospe Deposition (March 19, 2008), Exhibits 009 and 011.
[111] Rosenstein Deposition, Exhibit 014.
[112] Koutnik-Fotopoulos, Eileen, "Pharmacists Demand Fair Dispensing Fee," Pharmacy Times, March 24, 2006.
[113] Expert Report of Stephen W. Schondelmeyer, Pharm.D., Ph.D., National Association of Chain Drug Stores and National Community Pharmacists Association v. United States Department of Health and Human Services, et al., November 13, 2007, p. 8. *See also*, "Medicaid Outpatient Prescription Drugs," GAO, December 22, 2006; "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005," OIG A-06-06-00063, May 2006.

90. In sum, Medi-Cal was aware that any reduction in ingredient reimbursements would likely need to be offset by increases in dispensing fees.

VI. PROFITABILITY OF CALIFORNIA PHARMACIES

A. Introduction

91. In this section, I show that if Medi-Cal had relied on the but-for prices calculated by Dr. Leitzinger for its ingredient reimbursements, a substantial number of pharmacies would have lost money dispensing Sandoz drugs at issue to Medi-Cal recipients, even before accounting for any shortfall in dispensing fee.

B. Dr. Leitzinger's But-For Prices

92. Dr. Leitzinger calculates but-for prices by NDC and quarter, using transactions data produced by Sandoz.[114] Dr. Leitzinger starts by calculating a "net price," detailed below, which is a quarterly average price intended to represent an estimate of the amount wholesalers paid to Sandoz.[115]

93. He then adds a mark-up of between 3.7 and 5.4 percent over the "net price," depending on the year, to arrive at an estimate of the price that wholesalers' customers (i.e., retail pharmacies) pay.[116] In particular, Dr. Leitzinger states that he was asked to "[d]etermine the amounts (total ingredient cost only) that Medi-Cal would have reimbursed if the reported average wholesale prices ("AWPs") reasonably approximated the actual prices currently paid by wholesalers' customers."[117]

94. Therefore, Dr. Leitzinger's prices, each calculated as the "net price" plus a 3.7 to 5.4 percent mark-up, are the prices which Dr. Leitzinger evidently believes are a reasonable approximation of the prices paid by pharmacies. These prices are apparently what Dr. Leitzinger considers to be reasonable estimates of what Medi-Cal "would have reimbursed" for ingredient costs had Sandoz reported AWPs which "reasonably

[114] These data include information with respect to invoices, rebates, credits and chargebacks, and include transactions covering the period from January 2, 1996 through December 24, 2004. *See* CALI 3000000 and CALI 3000001, *see also* Leitzinger Report, pp. 8-11.
[115] Leitzinger Report, p. 8.
[116] Leitzinger Report, p. 11. The mark-ups are gross margins, which Dr. Leitzinger obtained from various years' issues of the "Industry Profile and Healthcare Factbook," Healthcare Distribution Management Association.
[117] Leitzinger Report, p. 2.

approximated the actual prices currently paid by wholesalers' customers."[118] In this respect, they are properly interpreted as but-for reimbursement prices.

95. I note, however, that there is some ambiguity in the prices Dr. Leitzinger intends to be his but-for price. To calculate damages, Dr. Leitzinger calculates an overcharge based on the difference between actual Medi-Cal reimbursement, and an amount which is 25 percent over his "net price."

96. It is not clear whether the but-for prices are meant to be the prices calculated by Dr. Leitzinger as his "net price" plus the 3.7 to 5.4 percent mark-up, or his "net price" plus a 25 percent margin.

97. To calculate a quarterly "net price," Dr. Leitzinger first aggregates invoice dollars for each NDC within a quarter on Sandoz' direct sales to wholesalers and distributers. He then reduces these gross sales figures by multiplying them by a "payment adjustment percentage" in order to account for rebates, chargebacks, and other credits Sandoz refunded to the wholesalers.

98. Dr. Leitzinger's "payment adjustment percentage" applied to gross sales in a given quarter is calculated as the ratio of total rebate, credit, and chargeback dollars for an NDC to total gross sales dollars, aggregated over an entire four-quarter period, covering the three quarters immediately preceding and including the given quarter.[119] The but-for price in each quarter for each NDC is then taken as the "net price" plus the mark-up calculated (in the above fashion) for the immediately preceding quarter. As described by Dr. Leitzinger:

> "For example, in order to calculate the average net price as of the beginning of 2000Q1, I first aggregate price concessions and gross revenue for January 1, 1999 through

[118] Leitzinger Report, p. 2. Dr. Leitzinger provides these "but-for" prices in his Exhibit 4.
[119] Dr. Leitzinger references Federal Register, September 16, 2004, Volume 69, Number 179, pp. 55763-55765, which he describes as indicating a "convention used by the U.S. government for Medicare reimbursement." *See* Leitzinger Report, p. 9 and fn 14. In principle, one would ideally like to link specific rebates, credits, or chargebacks to their originating transaction. However the data do not allow for this. Dr. Leitzinger excludes from his calculations transactions types which he categorizes as "Free Goods," "Returns," "Shortage," "Service Fee," and other uncategorized transactions. He includes transactions which he categorizes as "Allowances," "Rebates," Price Adj.," "Credit," "Sales," and "Chargebacks." In all cases where the transaction type is not categorized as "Sales," Dr. Leitzinger sets the quantity field to zero.

> December 31, 1999. I then calculate the ratio of price concessions to gross revenue. This ratio then is used to discount the gross price for 1999Q4. For example, if total price concessions equal $100 for January 1, 1999 through December 31, 1999 and total gross revenue equals $400 for that same period, the ratio is 0.25. If the gross price for 1999Q4 is $1.00, then the net price is $0.75 (calculated as $1.00 x (1-0.25)).”[120]

99. The $0.75 “net price” in Dr. Leitzinger’s example plus his mark-up is the but-for price he assigns to 2000Q1.

100. Because Medi-Cal sets its reimbursement amounts according to a standard package size for each drug, in order to match his but-for prices with Sandoz AWPs (Leitzinger Report, Exhibit 4), and to calculate damages, Dr. Leitzinger identifies the NDC which he has determined serves as the “leader” NDC for each of the California NDCs at issue, and applies the but-for price accordingly.[121]

C. In Dr. Leitzinger’s But-for World, Many Pharmacies Would Lose Money on Sandoz Prescriptions Reimbursed by Medi-Cal

101. Dr. Leitzinger’s but-for reimbursement prices on ingredient costs calculated with the 3.7 to 5.4 percent mark-up would have resulted in losses to a substantial share of pharmacies on the ingredient portion of Medi-Cal prescriptions during the relevant period.

102. For example, if a wholesaler purchases a drug for $10 in both 2002Q3 and 2002Q4 (net of rebates, credits and chargebacks), according to Dr. Leitzinger, the but-for Medi-Cal reimbursement for that drug in 2002Q4 would be $10.43.[122] Any pharmacy acquiring that same drug for more than $10.43 would lose money on the ingredient cost portion of reimbursement. These losses would be even greater when taking into account any shortfall between the dispensing fee and pharmacists’ dispensing costs.

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[120] Leitzinger Report, fn. 17.

[121] In his electronic back-up, Dr. Leitzinger has provided an Excel file called “Price Leader.xls,” which he uses to match NDCs at issue to their “leader.” Dr. Leitzinger provided no clear indication as to the source for this file or for how he identifies the “leader” NDC. In most cases, however, the “leader” is the 100-unit version of the drug.

[122] As discussed above, Dr. Leitzinger’s but-for reimbursement in any quarter is based on the prior quarter’s “net price” plus a mark-up. The 2002 mark-up applied by Dr. Leitzinger is 4.33%. In this example, I ignore the “Standard Package size” adjustment.

103. I have compared these but-for prices Dr. Leitzinger calculates for each of the Sandoz drugs at issue with the actual acquisition costs of those drugs for pharmacies purchasing through Cardinal Health, a large pharmaceutical wholesaler. According to my analysis, approximately 62 percent of California pharmacies would lose money on their Medi-Cal prescriptions dispensed with the Sandoz drugs at issue, even before accounting for any shortfall in dispensing fees. For parts of the state with few pharmacies participating in Medi-Cal, even one pharmacy choosing not to participate in Medi-Cal could substantially reduce patient access to prescription drugs.

104. Reimbursement would likely still not be sufficient to cover many pharmacists' acquisition costs on the Sandoz drugs at issue, even if reimbursed at 25 percent above the "net price." This is true even if the dispensing fees paid to California pharmacies were sufficient to cover their dispensing costs, which I have shown is in fact often not the case. I have repeated the analysis above, comparing actual ingredient reimbursements to the 25 percent margin over Dr. Leitzinger's "net price." I find that as many as about 31 percent of participating pharmacies would lose money on their overall purchases of Sandoz drugs at issue which were subsequently reimbursed by Medi-Cal, even before accounting for any shortfall in dispensing fees.

VII. CRITIQUE OF DR. LEITZINGER'S DAMAGES ANALYSIS

A. Introduction

105. In analyzing damages, Dr. Leitzinger was instructed by counsel to calculate California's "overpayment … excluding overpayments that arise from any and all claims where the reimbursement amount paid by Medi-Cal (total ingredient cost only) was less than 25 percent above the average net price paid by wholesalers to Sandoz for the relevant pharmaceutical product."[123]

106. Dr. Leitzinger fails to provide any explanation or economic justification for his 25 percent margin threshold. He apparently followed instruction of counsel. It is not evident from Dr. Leitzinger's report how the 25 percent threshold is interpreted.

[123] Leitzinger Report, p. 3.

107. In order to derive the purported ingredient cost "overpayment," Dr. Leitzinger first drops any claims for which the actual reimbursement was less than 25 percent above his calculated "net price."

108. For the remaining claims, the "overpayment" is calculated as the difference between the actual ingredient reimbursement (the reimbursement amount from the claims data less the dispensing fee),[124] and the amount that is 25 percent above the "net price" in any quarter for each drug.[125] Total alleged overcharges are the sum of over all relevant drugs and quarters.

109. In approximately 16 percent of claims, Dr. Leitzinger is unable to calculate a "net price."[126] He fills in these gaps using claims for which he is able to calculate a "net price." Specifically, he sums up to get total overcharges and total actual reimbursement amounts by NDC over the entire period, and he derives the ratio of overcharges to reimbursement.[127] He applies this ratio to the total reimbursement amounts for claims in which he is unable to match a "net price."

B. The Evidence of an Adverse Effect on Patient Access is Reasonable

110. Dr. Leitzinger does not analyze the impact of a lower ingredient reimbursement on pharmacy profitability and the implications for access in his Report, as I detailed above. He does, however, recognize it as an issue. "I understand that Dey (and its experts) have claimed that reduced ingredient cost reimbursement would adversely affect access by program participants to pharmacy services and that this reduction would, in turn, lead Medi-Cal to increase the standard dispensing fee associated with reimbursement."[128]

111. Dr. Leitzinger has stated that "economic proof" of such an adverse effect would require: "1) the standard dispensing fees associated with Medi-Cal reimbursement during

[124] The reimbursement amount and dispensing fee are provided in the claims data in fields called CLM_REIMBRSMNT_AMT_349 and CLM_PROFNL_FEE_AMT_381, respectively. Where the dispensing fee is given as zero in the data, Dr. Leitzinger fills in the standard dispensing fee. *See* Leitzinger Report, p. 7.
[125] The applicable "net price" is the one for the Standard Package size. Leitzinger Report, pp. 10 and 11.
[126] Leitzinger Report, p. 12. As I discuss in more detail below, the Sandoz transaction data Dr. Leitzinger uses to calculate his "net price" does not go back before 1996. In other cases, there are NDC-quarters in which no sales are observed in the Sandoz data.
[127] Dr. Leitzinger includes in this calculation, claims for which he found negative overcharges.
[128] Leitzinger Report, p. 13.

the period in question here did not cover dispensing costs; 2) reimbursement of ingredient costs at amounts that were no more than 25 percent above net manufacturer prices to wholesalers, taken in combination with the standard dispensing fees that were paid during the period, would not have provided overall reimbursement sufficient to induce pharmacies to dispense Medi-Cal prescriptions; and 3) the resulting decline in the ability of Medi-Cal participants to access prescriptions would have prompted a decision by Medi-Cal to increase the standard dispensing fee."[129]

1. Medi-Cal dispensing fees were generally insufficient to cover pharmacy dispensing costs.

112. With regard to Dr. Leitzinger's first point, I have explained in detail in Section V that there is ample evidence that dispensing fees were generally not high enough to cover many pharmacies' dispensing costs. A number of studies I cited above found that Medi-Cal's dispensing fees were not adequate to compensate many especially high-cost pharmacies.

2. Dr. Leitzinger's 25 percent margin would not be sufficient to cover losses on dispensing costs for many drugs.

113. Regarding Dr. Leitzinger's second point, I demonstrated that the 25 percent margin likely would provide insufficient profit over ingredient cost, particularly on low-cost drugs, to compensate for many, if not most, per-prescription shortfalls on dispensing costs.

114. Margins on many low-cost drugs would likely need to be substantially greater than 25 percent in order for pharmacies to break even on dispensing generic drugs to Medi-Cal patients. This is because 25 percent applied to a low dollar price will result in a low dollar ingredient cost profit. This is a particular concern in the case of many generic drugs whose prices have been competed down to low levels.

115. Consider the example of atenolol, NDC 00178150610, which is the top drug reimbursed by Medi-Cal among the drugs in this matter. According to Dr. Leitzinger, the "net price" plus a 25 percent margin per 30-pill prescription for prescriptions dispensed from a 1000-pill package in the third quarter of 2000 would be $0.54. The average cost

[129] Leitzinger Report, p. 14.

of acquiring these pills, according to Dr. Leitzinger's methodology, was $0.45. Thus the pharmacist would earn $0.09 on the ingredient cost.[130]

116. However, this would fail to cover the shortfall on the dispensing fee for most pharmacies. Assuming a $7.40 dispensing cost, as estimated in the Myers and Stauffer study for the year 2000,[131] and a $4.05 dispensing fee, the pharmacist would face a $3.35 shortfall on the dispensing cost side. The $.09 earned on the ingredient cost owing to the 25 percent allowance Dr. Leitzinger assumes, would leave the pharmacist with a $3.26 loss, which is 724% of the drug acquisition cost.

3. Lowering ingredient cost reimbursement would have required that the State of California seriously consider raising dispensing fees.

117. Regarding Dr. Leitzinger's third point, a pharmacist's decision as to whether or not to participate in Medi-Cal will depend importantly on whether it earns an adequate profit. Evidence in the record shows that the California Pharmacists Association has lobbied California Legislators against policy proposals which they believed would threaten their ability to remain profitable. There is evidence that California policymakers did in fact understand the interrelationship between dispensing fees and ingredient reimbursement, and that they have shown resistance in past to changing reimbursement policy in light of pharmacy access concerns. Moreover, in September 2004, the dispensing fee was raised in conjunction with an increase in the discount off of AWP.

118. Thus, a problem of patient access stemming from lower ingredient cost reimbursements would have required that the State of California seriously consider raising dispensing fees.

4. Dispensing fee shortfalls would have been substantial without higher ingredient margins.

119. Eliminating pharmacy margins on the ingredient cost side, as would occur in Dr. Leitzinger's but-for world, would require an increase in dispensing fees if pharmacy

[130] Per Exhibit 4 in Dr. Leitzinger's report, the 2000Q3 but-for price per 1000-pill package of atenolol, NDC 00781150610 (which Dr. Leitzinger calculates as the "net price" plus a 4.43 percent mark-up), is $15.16, or $0.454 per 30-pill prescription. The "net price" plus a 25 percent margin is therefore equal to $0.543 (which equals (0.454/1.0443)*1.25). Rounding to the penny, the ingredient side profit is therefore 0.54 minus 0.45 or $0.09. I note that this is conservative, for it does not account for any lump sum reimbursement reduction under Medi-Cal's reimbursement methodology in effect at the time.
[131] Myers and Stauffer, Pharmacy Reimbursement, p. 28.

profitability were to be preserved. I have analyzed the Medi-Cal dispensing fees relative to various estimates of dispensing costs, and find that as a reasonable approximation, dispensing fee shortfalls, if not subsidized by higher ingredient margins, would have cost participating pharmacies $35 million (Myers and Stauffer) to $81 million (Grant Thornton) on claims at issue. Specifically, as an approximation of pharmacy dispensing cost, I use estimates from the three separate studies I discussed in Section V, and apply an inflation adjustment in order to arrive at dispensing costs by year. Using Medi-Cal's actual dispensing fees, I calculate the difference in the dispensing fee and the estimated dispensing cost. I then aggregate these differences over all claims at issue.[132]

C. Dr. Leitzinger Fails to Account for Alternate Reimbursement Methodologies Considered By Medi-Cal

1. AWP was not the only benchmark available to California policy-makers.

120. Medi-Cal's ingredient reimbursement formula was a simple comparison of AWP less a percent discount, the FUL, and the MAIC. Recall that the MAIC was based on AWP, and according to one Medi-Cal representative, was not very effective.[133] Moreover, Medi-Cal knew that AWP did not represent actual acquisition costs, and had access to estimates of the difference between AWPs and actual acquisition costs. Therefore, California policy-makers could have enhanced or altered the reimbursement methodology applied by Medi-Cal to account for pricing benchmarks other than AWP, or taken larger discounts off AWP.

121. For example, WAC prices reported by FDB were available to the state of California. California officials were aware that WAC served as a reimbursement basis in many other states, including for example, Colorado and Maryland.[134] As shown in Exhibit 3, a simple comparison of published WACs and published AWPs – information readily available to the State of California – reveals that WAC prices are substantially below AWPs for Sandoz drugs.

[132] I used the Medical Care CPI, available at <ftp://ftp.bls.gov/pub/time.series/cu/cu.data.15.USMedical>, accessed July 29, 2009.
[133] Rosenstein Deposition, pp. 140-141.
[134] Rosenstein Deposition, p. 6, Exhibits 011, 021.

122. Sandoz also provided, directly and/or indirectly, information on its AMPs to Medi-Cal.[135] Medi-Cal was aware that AMP also is lower than AWP,[136] and information was also available that AMP was lower than WAC.[137] Therefore, in order to reduce its reimbursement costs, California policymakers could have utilized available information on manufacturers' AMPs.

123. As a third alternative, California policy-makers could have adjusted its MAIC program so as to make it more effective. For example, California could have followed the approach of Wisconsin, which bases its MAC prices in part on provider invoices and information from wholesalers, and which reviews its MACs on a quarterly basis.[138] Alternatively, California could have looked to Kentucky, which outsourced the setting of MAC prices to First Health Services Corporation.[139]

124. Finally, reimbursement policy could have used different reimbursement formulae for generics versus branded drugs. I pointed out that several reports from OIG indicated that the relationship between AWP and acquisition cost differed substantially for branded and generic drugs. Consistent with this, a CMS report on reimbursements by state showed that by September 2004, many other state Medicaid agencies reimbursed using greater discounts off AWP for generic drugs than for branded drugs.[140] For example, Colorado reimbursed at AWP-13.5% for brands, but at AWP-35% for generics. Connecticut reimbursed at AWP-12% for brands and AWP-40% for generics.[141]

2. California policy-makers considered many of these alternatives.

125. During the 1995 to 1996 timeframe, California policy-makers proposed legislation to revise Med-Cal's reimbursement methodology by changing the EAC

[135] AMPs were provided directly from 1991 to 1997 (SANDOZCALI3000028-1273) and indirectly through the unit rebate amount information from CMS. AMPs were also provided with supplemental rebate payments for certain drugs. *See* Miller Deposition (September 24, 2008), Exhibits 007, 010
[136] Miller Deposition (October 22, 2008), p. 317.
[137] "Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices," OIG, June 2005, pp. 64.
[138] *Medicaid Briefing Papers*, Governors Pharmacy Reimbursement Commission, November 17, 2005 (WI-Prod-AWP-111655-656).
[139] Since 2004, First Health Services Corporation has been administering Kentucky Medicaid's MAC program. *See* Kentucky Pharmacy MAC List, <https://kentucky.fhsc.com/Pharmacy/providers/mac.asp>, accessed July 29, 2009.
[140] Medicaid Prescription Reimbursement Information by State, CMS, September 2004.
[141] Medicaid Prescription Reimbursement Information by State, CMS, September 2004.

calculation to the lower of AWP-10% and WAC+7%.[142] Medi-Cal was aware that a number of other states used WAC as a basis for reimbursement.[143] Subsequently, the 2000 Task Force cited above also discussed using WAC as a basis for reimbursement, and noted that other states were using WAC.[144]

126. Medi-Cal also considered different reimbursement adjustments for brand and generic drugs.[145] Mr. Rosenstein testified in reference to applying the 17 percent discount to AWP, which represented Myers and Stauffer's approximate estimate of the average by which AWPs exceeded actual single-source drug acquisition costs, "… we set this rate assuming we could do additional work on generics through a MAC."[146]

127. As part of a 2002-2003 budget trailer, the Legislature adopted a bill which changed the calculation of MAIC prices to be based them on the "average price paid by pharmacies to a wholesale drug distributor…" rather than on AWP. The new MAIC methodology would have involved surveying wholesalers.[147] However, the new program was never implemented.[148]

128. In sum, California policy-makers were aware of the array of alternatives to its use of AWP as the basis of a reimbursement formula (including the possibility of applying larger discounts to AWP), in establishing the EAC. Therefore, they could have enacted and implemented policies to address the alleged "excessive prices" that Medi-Cal paid.[149]

129. I have considered the effect of one proposal considered by Medi-Cal on Medi-Cal's expenditure on Sandoz drugs. As far back as at least 1995, California policy-makers had proposed replacing the AWP-5% EAC methodology with an EAC calculated as the minimum of WAC+7% and AWP-10%.[150] In this analysis, I assume that this

[142] Rosenstein Deposition, pp. 123-133 and Exhibits 009 - 011, see also Gorospe Deposition (March 19, 2008), Exhibit 026.
[143] Rosenstein Deposition, p. 5 and Exhibit 011.
[144] Rosenstein Deposition, Exhibit 021.
[145] Rosenstein Deposition, pp. 230-232.
[146] Rosenstein Deposition, p. 231.
[147] Rosenstein Deposition, pp. 245-249 and Exhibit 028, p. 10.
[148] Gorospe Deposition (September 22, 2008), pp. 447-449.
[149] First Amended Complaint, p. 1.
[150] Rosenstein Deposition, Exhibits 009 and 010.

proposal would have been enacted,[151] effective July 1, 1996, the beginning of the California budget fiscal year. I also assume that in September 2004, the policy would have changed such that EAC would have been the lesser of AWP-17% and WAC+7%.

130. Given these assumed changes to California's reimbursement methodology, I have recalculated what California would have reimbursed for ingredient costs on Sandoz drugs at issue.[152] Had the State of California implemented the proposal it considered in 1995, it would have paid about $65 million less for Sandoz drugs at issue. Figure 2 shows the distribution of the basis of payment on claims resulting from my analysis.

Figure 2

Basis of Payment	Claims Percent
WAC plus 7%	61%
FAC	33%
AWP minus disc.	1%
EAC	0%
U&C	5%
Total	**100%**

D. Dr. Leitzinger Underestimates Wholesaler Mark-Ups on Generic Drugs

131. Dr. Leitzinger's 3.7 to 5.4 percent mark-ups used to derive his but-for price appear to be annual average gross margins, and also apparently blend brand and generic drugs.[153] However, several studies of the pharmaceutical wholesale industry indicate that generic margins can be several times the margins on brand.

132. Wholesalers play a different role in the distribution of generic drugs than they do in branded drugs. For branded drugs, wholesalers effectively act as order takers, shipping the branded drugs ordered by their retail pharmacy customers. As such, wholesalers have little bargaining power when negotiating with branded manufacturers. In contrast, wholesalers can have significant bargaining power when negotiating with generic manufacturers. Many retailers do not require a specific manufacturer's generic drug and

[151] The proposal included other policy recommendations, including proposals to adjust the process for supplemental rebate contracting, and adjusting reimbursement on medical supplies. I do not account for these in this analysis.
[152] I do not consider the dispensing cost component in this analysis.
[153] Dr. Leitzinger's sources are various years' issues of the *Industry Profile and Healthcare Handbook*; *See* Leitzinger Report, fn. 20.

are willing to accept the particular AB-rated generic of the wholesaler's choosing. Recognizing this, wholesaler created their own buying programs to pool their retail customers' buying power and negotiate discounts from generic manufacturers for generic drugs. Thus, it is reasonable to believe that wholesaler returns on generic drugs will be higher than on branded drugs.

133. Evidence suggests that this is, in fact the case:

- An October 2003 FitchRatings report states: "… distributor margins are frequently three to five times greater on generic than on branded drugs."[154]
- A JP Morgan research report states that "… generics generally provide a better gross margin to the distributor than their branded counterparts." JP Morgan estimated that the gross margin on generics was generally three to five times higher than for branded drugs.[155]
- A February 2002 Bear Stearns report analyzed several generic entry scenarios. Pre-entry, they assume a brand gross margin of 4 to 5 percent. In a scenario of exclusive entry, the resulting generic gross margin is 10 to 20 percent.[156]

134. Generics represent a relatively small share of overall wholesaler revenue.[157] Therefore, a mark-up measure based on overall product mix would be expected to be heavily weighted toward the brand mark-ups. Thus, the evidence suggests that Dr. Leitzinger has substantially understated wholesaler margins on generic drugs.

E. Dr. Leitzinger's Alleged "Overpayments" for 1994 and 1995 Are Excessive

135. The Sandoz transaction used by Dr. Leitzinger begins in January 2, 1996, while his damages calculations start on January 1, 1994. To deal with this missing data problem, Dr. Leitzinger fills in the 1994 and 1995 "net prices" using the gap-filling

[154] FitchRatings, "The Generic Equation: The Emergence of Generic Pharmaceuticals and Their Impact on Pharmaceutical Wholesalers," October 14, 2003, p. 2. *See also*, 2004 McKesson Corporation Gross Annual Report, <http://www.mckesson.com/en_us/McKesson.com/Investors/Financial%2BInformation/Annual%2BReports.html>, p. 30, accessed July 28, 2009.
[155] JP Morgan, North American Equity Research, April 21, 2003, pp. 14-16.
[156] Bear Stearns, "Health Care Distribution: Analyzing the Shifts From Brands to Generics, Chains to mail Order, Growth to Defensive?" February 2002, pp. 53-55.
[157] According to the *2004 Industry Profile and Healthcare Handbook*, generic revenues were about 16 percent of distributor net prescription drug sales. *See 2004 Industry Profile and Healthcare Handbook*, HDMA, p. 13. FitchRatings reports generics represent about 10 percent of distributor top-line pharmaceutical revenue. *See* FitchRatings, "The Generic Equation: The Emergence of Generic Pharmaceuticals and Their Impact on Pharmaceutical Wholesalers," October 14, 2003, p. 2.

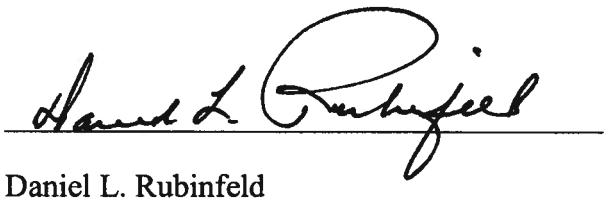
methodology described above.[158] However, Dr. Leitzinger applies an overcharge ratio, which is calculated for each NDC over the entire period. This approach is inappropriate, and exaggerates overcharges if his overcharge percentage for an NDC is increasing over time.

136. I have reviewed Dr. Leitzinger's overcharge calculation on a year-by-year basis, and find that it is generally the case his overcharge ratio has been increasing. To account for this, I have rerun Dr. Leitzinger's analysis where, rather than applying an average overcharge ratio across the entire period, by NDC, I have calculated yearly average overcharge ratios by NDC. Applying the 1996 ratio to 1994 and 1995, I find that in 1994 and 1995, "overpayments" decline by more than $4 million, or about 45 percent for those years.[159]

[158] The 1994 and 1995 claims represent about 10 percent of Dr. Leitzinger's total Medi-Cal claims, but about 70 percent of the claims in which Dr. Leitzinger was unable to calculate a net price.
[159] Overall, this adjustment lowers "overpayments" by about $4.5 million.

I declare, under penalty of perjury, that the foregoing is true and correct to the best of my knowledge and belief.

Submitted this 30th day of July 2009,



Daniel L. Rubinfeld

Exhibit 2a: California Medi-Cal Claims - Basis of Payment (1994-2004)

Year	Number of Claims					
	FAC	EAC	AWP-Disc	Usual & Customary	Other	TOTAL
1994	447,291	0	52,924	68,945	15	**569,175**
1995	631,346	0	52,133	93,088	25	**776,592**
1996	729,286	0	63,574	125,762	114	**918,736**
1997	690,233	0	114,817	135,539	190	**940,779**
1998	677,774	30,659	155,264	166,175	32	**1,029,904**
1999	859,339	55,103	139,665	164,208	12	**1,218,327**
2000	953,923	46,768	178,488	160,756	6	**1,339,941**
2001	1,058,529	38,989	224,448	233,479	10	**1,555,455**
2002	1,168,482	61,138	237,204	126,622	6	**1,593,452**
2003	1,253,069	257,143	426	132,202	0	**1,642,840**
2004	1,142,333	209,892	711	137,649	0	**1,490,585**
TOTAL	**9,611,605**	**699,692**	**1,219,654**	**1,544,425**	**410**	**13,075,786**

Year	Claims %				
	FAC	EAC	AWP-Disc	Usual & Customary	Other
1994	79%	0%	9%	12%	0%
1995	81%	0%	7%	12%	0%
1996	79%	0%	7%	14%	0%
1997	73%	0%	12%	14%	0%
1998	66%	3%	15%	16%	0%
1999	71%	5%	11%	13%	0%
2000	71%	3%	13%	12%	0%
2001	68%	3%	14%	15%	0%
2002	73%	4%	15%	8%	0%
2003	76%	16%	0%	8%	0%
2004	77%	14%	0%	9%	0%
TOTAL	**74%**	**5%**	**9%**	**12%**	**0%**

Notes:

[1] Includes claims from January 1, 1994 until December 31, 2004 based on service date field, CLNDR_DT.

[2] Claims with CLM_REIMBRMNT_AMT_349 <= 0 are dropped.

[3] The basis of payment for a claim is from the data field CLM_PMT_CLCLTN_CD_830.

[4] Usual & Customary is defined as CLM_BILL_AMT < (CLM_ALOWD_AMT_380 + CLM_PROFNL_FEE_AMT_381).

[5] The discount on AWP was 5 % until June 30, 2004, 10 % from July 1, 2004 until August 31, 2004, and 17 % from September 1, 2004 onwards.

Sources:

Medi-Cal claims data (Disc ID: 21A and 21B); Claims reversals are dropped from the data using Dr. Leitzinger's methodology.

Letter from Nicholas Paul of the California Bureau of Medi-Cal Fraud and Elder Abuse to Toni-Ann Citera of Jones Day, November 15, 2007.

Exhibit 2b: California Medi-Cal Claims - Basis of Payment (1994-2004)

Year	Dollar Value of Claims					
	FAC	EAC	AWP-Disc	Usual & Customary	Other	TOTAL
1994	$ 5,347,083	$ -	$ 1,909,593	$ 1,630,222	$ 188	**$ 8,887,086**
1995	$ 9,690,389	$ -	$ 1,062,540	$ 2,685,738	$ 190	**$ 13,438,857**
1996	$ 11,052,994	$ -	$ 1,657,587	$ 3,866,144	$ 731	**$ 16,577,456**
1997	$ 9,878,318	$ -	$ 2,714,692	$ 4,086,992	$ 1,185	**$ 16,681,187**
1998	$ 10,550,986	$ 673,093	$ 4,509,286	$ 4,628,797	$ 1,256	**$ 20,363,418**
1999	$ 13,370,924	$ 1,302,274	$ 6,630,511	$ 5,443,097	$ 1,052	**$ 26,747,859**
2000	$ 13,003,575	$ 1,203,635	$ 10,405,125	$ 6,267,320	$ 740	**$ 30,880,394**
2001	$ 14,701,655	$ 1,036,058	$ 13,474,493	$ 7,672,234	$ 474	**$ 36,884,913**
2002	$ 16,044,316	$ 2,589,953	$ 12,311,617	$ 3,847,679	$ 232	**$ 34,793,797**
2003	$ 19,122,657	$ 13,809,223	$ 40,651	$ 3,383,104	$ -	**$ 36,355,634**
2004	$ 18,323,490	$ 10,856,321	$ 62,660	$ 3,315,116	$ -	**$ 32,557,586**
TOTAL	**$ 141,086,385**	**$ 31,470,557**	**$ 54,778,755**	**$ 46,826,442**	**$ 6,048**	**$ 274,168,187**

Year	Dollars %				
	FAC	EAC	AWP-Disc	Usual & Customary	Other
1994	60%	0%	21%	18%	0%
1995	72%	0%	8%	20%	0%
1996	67%	0%	10%	23%	0%
1997	59%	0%	16%	25%	0%
1998	52%	3%	22%	23%	0%
1999	50%	5%	25%	20%	0%
2000	42%	4%	34%	20%	0%
2001	40%	3%	37%	21%	0%
2002	46%	7%	35%	11%	0%
2003	53%	38%	0%	9%	0%
2004	56%	33%	0%	10%	0%
TOTAL	**51%**	**11%**	**20%**	**17%**	**0%**

Notes:

[1] Includes claims from January 1, 1994 until December 31, 2004 based on service date field, CLNDR_DT.

[2] Claims with CLM_REIMBRMNT_AMT_349 <= 0 are dropped.

[3] The basis of payment for a claim is from the data field CLM_PMT_CLCLTN_CD_830.

[4] Usual & Customary is defined as CLM_BILL_AMT < (CLM_ALOWD_AMT_380 + CLM_PROFNL_FEE_AMT_381).

[5] The discount on AWP was 5 % until June 30, 2004, 10 % from July 1, 2004 until August 31, 2004, and 17 % from September 1, 2004 onwards.

Sources:

Medi-Cal claims data (Disc ID: 21A and 21B); Claims reversals are dropped from the data using Dr. Leitzinger's methodology.

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